At-a-glance: mRNA COVID-19 Vaccines

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

Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)
EUA	Issued December 11, 2020	Issued December 18, 2020
Fact sheet	• Health care providers • Recipients/caregivers	• Health care providers • Recipients/caregivers
ACIP	Interim recommendation for use: Persons aged ≥18 years for prevention of COVID-19	Interim recommendation for use: Persons aged ≥16 years for prevention of COVID-19
Dose	30 mcg **(0.3 mL each)**	100 mcg **(0.5 mL each)**
Schedule	**First dose:** Day 0 **Second dose:** Day 21	**First dose:** Day 0 **Second dose:** Day 28
Storage and handling	• **Long-term storage:** -70°C (dry ice) • **Refrigeration:** 2°C–8°C for up to 5 days • **Room temp:** up to 5 hours (unpunctured) **Must be at room temp at least 30 minutes before dilution* • **After first use:** Room temp up to 6 hours	• **Long-term storage:** -20C • **Refrigeration:** 2°C–8°C for up to 30 days • **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.* • **After use:** Room temp up to 6 hours
Efficacy	95%: Primary analysis of Phase III trial data in 43,538 volunteers beginning 7 days after second dose	94.1%: Primary analysis of Phase III trial data in >30,000 volunteers beginning 14 days after second dose
Contraindications	Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine	
Postvaccination symptoms	• **Local:** pain, swelling, erythema at the injection site, localized axillary lymphadenopathy (80%–89% of vaccinated persons*) • **Systemic:** fever, fatigue, headache, chills, myalgia, arthralgia (55%–83% of vaccinated persons*; acetaminophen or ibuprofen may be used) • These symptoms tend to be more common after the second dose and resolve 1–3 days after vaccination. • Anaphylaxis following vaccination was not observed in clinical trials. • 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*	
Phase III study	Walsh, et al. *NEJM*. 2020.	Jackson, et al. *NEJM*. 2020.

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

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Quick Links

- CDC: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States
- CDC: Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine
- CDC: Frequently Asked Questions about COVID-19 Vaccination
- FDA: Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions

Administration

- **Dosing interval:** Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated.
- **Extra doses:** More than five doses may be obtainable from the Pfizer-BioNTech vaccine vials. FDA is advising that it is acceptable to use every **full dose** obtainable from each vial; however, since the vials are preservative free, it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one dose.
- **Interchangeability:** NOT interchangeable with other COVID-19 vaccine products; complete the vaccine series with the same product.
  - > If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.
- **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.

Storage and handling

- Complete storage and handling information can be found in the fact sheets for health care providers in the table above.
- For both vaccines, never refreeze.

At-a-glance: mRNA COVID-19 Vaccines (continued)

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

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
- Review CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites.
- See table below for the ingredients within each vaccine.

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.

At-a-glance: mRNA COVID-19 Vaccines (continued)

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

Pregnancy and lactation

- **Pregnancy:** No data are available on the safety of COVID-19 vaccines in pregnant women; studies are ongoing, and more are planned.
  - > 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:** 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 infection and testing

- **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.
  - > Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision making.
- **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.

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

Considerations related to infection and testing *Continues.*

- **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.

At-a-glance: mRNA COVID-19 Vaccines (continued)

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Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

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

Source: Adapted from CDC's Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States; Appendix A.