COVID-19 astho

Issue Brief

COVID-19 Vaccine Comparison

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Three COVID-19 vaccines, <u>Pfizer-BioNTech</u>, <u>Moderna</u>, and <u>Johnson & Johnson</u> (J&J) are available in the United States. A listing of key details for each vaccine can be found below, which has evolved over time. This list is not exhaustive.

Vaccine Administration for Primary Series and Additional Doses

Pfizer-BioNTech/COMIRNATY		Moderna/SPIKEVAX		Janssen (J&J) Vaccine
Vaccine		Vaccine		
Primary Series		Primary Series		Primary Series
Update: 6 months to 4 years old	Emergency Use Authorization (EUA). Administered by intramuscular (IM) injection using 0.2 mL (3 µg), mixed with a 0.9% sodium chloride diluent, with a maximum of 10 doses per vial, using a vial with a maroon cap and a label with a maroon border. Three shots are required. The first and second doses are separated by 3-8 weeks and the second and third doses are separated by at least 8 weeks.	Update: 6 months to 5 years old	EUA. Administered by IM injection using 0.25 mL (25 μg), not mixed with a diluent, with a maximum of 10 doses per vial, using a vial with a dark blue cap and a label with a magenta border. Two shots are required, separated by 4-8 weeks.	No J&J vaccine authorized for this age group.
5-11 years old	EUA. Administered by IM injection using 0.2 mL (10 μg), mixed with a 0.9% sodium chloride diluent, with a maximum of 10 doses per vial, using a vial with an orange cap and a label with an orange border. Two shots are required, separated by 3-8 weeks.	Update: 6-11 years old	EUA. Administered by IM injection using 0.5 mL (50 µg), not mixed with a diluent, with a maximum of 5 doses per vial, using a vial with a dark blue cap and a label with a purple border^. Two shots are required, separated by 4-8 weeks. ^The cartons and vial labels state "BOOSTER DOSES ONLY." This presentation may be used to provide primary series doses to	No J&J vaccine authorized for this age group.

	Pfizer Wall Chart for Healthcare Providers		individuals 6 years through 11 years of age.		
12-15 years old	EUA. Administered by IM injection using: Purple cap vial: A 0.3 mL dose (30 μg), mixed with a 0.9% sodium chloride diluent, with a maximum of six doses per vial, OR Gray cap vial: A 0.3 mL dose (30 μg) with a maximum of six doses per vial (Do not dilute this formulation). Two shots are required, separated by 3-8 weeks (21 days).	Update: 12-17 years old	EUA. Administered by IM injection using 0.5 mL (100 μg), not mixed with a diluent, using a vial with a red cap and a label with a light blue border. Two shots are required, separated by 4-8 weeks.	No J&J vaccine a age group.	authorized for this
16 years and older	Fully licensed (Biologics License Application) under the name Comirnaty. Administered by IM injection using either: Purple cap vial: A 0.3 mL dose (30 µg), mixed with a 0.9% sodium chloride diluent, with a maximum of six doses per vial, OR Gray cap vial: A 0.3 mL dose (30 µg) with a maximum of six doses per vial (Do not dilute this formulation). Two shots are required, separated by 3-8 weeks.	18 years and older	Fully licensed (Biologics License Application) under the name SPIKEVAX. Administered by IM injection using a 0.5 mL (100 µg) dose, not mixed with a diluent, using a vial with a red cap (Moderna/SPIKEVAX. Two shots are required, separated by 4-8 weeks.	18 years and older	EUA. Administered by IM injection using a 0.5 mL dose with a maximum of five doses per vial, using a vial with a blue cap. One shot is required.
Additional D	Pose for People with Modera	te to Severe	Immunocompromise		
People ages five years and older should get an <u>additional (third) primary shot</u> of Pfizer-BioNTech COVID-19 vaccine given 28 days after the second dose using the <u>vial and cap colors</u> referenced above, for the appropriate age group.		Update: Ages 6-months to 17 years may get an additional (third) primary shot of Moderna COVID-19 vaccine given at least 4 weeks after the 2 nd dose, using the vial and cap colors referenced above, for the appropriate age group. People ages 18 years and older should receive an additional primary dose (third dose) of Moderna vaccine		People ages 18 years and older who received J&J for their first dose should receive an additional primary dose of mRNA vaccine* at least 28 days later. If Moderna COVID-19 vaccine is used for the second dose, administer a 0.5 ml (100 µg) dose using a vial with a red cap. See Clinical Guidance for COVID-19 Vaccination for more information.	

(0.5 mL) at least 28 days after the second dose using a vial with a red cap (Moderna/SPIKEVAX).

Vaccine Administration of Booster, Second Booster, and Heterologous Booster Doses

Pfizer-BioNTech/COMIRNATY	Moderna/SPIKEVAX	Janssen (J&J) Vaccine
Vaccine	Vaccine	
First Booster Dose	First Booster Dose	First Booster Dose
6-months to 4 years old: No booster dose	6-months to 5 years old: No booster	
authorized.	dose authorized.	
5-11 years old:	6-17 years old: No booster dose	
A single Pfizer-BioNTech COVID-19 Vaccine	authorized.	
booster dose 0.2 mL (10 μg), supplied in		
multiple dose vials with an orange cap and a		
label with an orange border should be		
administered, after dilution, to individuals 5		
through 11 years of age, at least 5 months after completing a primary series of the		
Pfizer-BioNTech COVID-19 Vaccine.		
Filzer-biolytecti COVID-13 vaccine.		
12 years and older:	18 years and older:	18 years and older:
A single booster dose should be administered	A single booster dose* (mRNA	A single booster dose* (mRNA
to all individuals 12 and older, *** at least	preferred) should be administered to	preferred) should be
five months after completion of the primary	all individuals ages 18 years and	administered to persons ages 18
(two-dose) series.	older , [†] at least five months after	years and older at least two
	completion of the primary (two dose)	months after primary vaccination
 Ages 12 to 17 years with moderate 	series.	(one-dose) with the J&J COVID-19
to severe immunocompromise who		vaccine. mRNA vaccine is
received an additional primary	Ages 18 years and older	preferred. ⁺
Pfizer-BioNTech dose (third dose),	with moderate to severe	
should also receive a booster dose	immunocompromise who	
(fourth dose) (0.3 ml) of Pfizer-	received a two-dose mRNA	
BioNTech vaccine with a <u>purple cap</u> <u>vial</u> or <u>gray cap vial</u> at least three	primary series and an	
months after completing their	additional primary dose (three total mRNA doses)	
primary series.	can receive a single COVID-	
Ages 18 years and older with	19 booster dose * (mRNA	
moderate to severe	preferred) at least three	
immunocompromise who received a	months after completing	
two-dose mRNA primary series, and	their third mRNA vaccine	
an additional primary dose (three	dose.	
total mRNA doses) should receive a		
single COVID-19 booster dose (Pfizer-	Either Moderna COVID-19 Vaccine	
BioNTech, Moderna, or J&J) at least	supplied in a vial with a red cap (0.25	
three months after completing their	mL injection volume) or Moderna	
third mRNA vaccine dose.	COVID-19 Vaccine supplied in a vial	

	with a <u>dark blue cap</u> (0.5 mL injection volume) can be used to administer a 50 μg booster dose.	
Second Booster Dose	Second Booster Dose	Second Booster Dose
Adults 50 years and older should receive a second booster dose using an mRNA COVID-19 vaccine at least four months after the first booster dose. People ages 12 years** and older who are moderately or severely immunocompromised should receive a second booster dose using an mRNA COVID-19 vaccine at least four months after the first booster dose.*	Adults 50 years and older should receive a second booster dose using an mRNA COVID-19 vaccine at least four months after the first booster dose. People ages 18 years and older who are moderately or severely immunocompromised should receive a second booster dose of mRNA vaccine, at least four months after their first booster dose.	Adults ages 18-49 years who received J&J COVID-19 vaccine as both their primary series dose and booster dose, may receive a second booster dose of an mRNA COVID-19 vaccine at least four months after the first J&J booster dose. Adults 50 years and older who first received J&J, regardless of what type of booster they received, should receive a second booster dose using an mRNA COVID-19 vaccine at least four months after the first booster dose. See Clinical Guidance for COVID-19 Vaccination for more information.

^{*} Although mRNA vaccines are preferred, J&J/Janssen COVID-19 vaccine may be considered in some situations.

Vaccine Information for Children who Transition from a Younger to an Older Age Group

CDC recommends vaccine recipients receive the recommended age-appropriate vaccine product and dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group during the primary series, they should receive the vaccine product and dosage for the older age group for all subsequent doses. FDA emergency use authorization (EUA) allows for different dosing for certain age transitions, which are not considered vaccine administration errors and do not need to be reported to the Vaccine Adverse Event Reporting System (VAERS).

- Moderna COVID-19 Vaccine: For Children who Transition from a Younger to Older Age Group.
- Pfizer-BioNTech COVID-19 Vaccine: For Children who Transition from a Younger to Older Age Group.

Side Effects

The benefits of vaccine outweigh the risks. However, side effects have been reported. <u>Serious health events after COVID-19 vaccination are rare</u>. Common side effects include pain, redness and swelling at the injection site, tiredness, headache, muscle pain, chills, nausea, joint pain, and fever. Less common severe side effects

^{**} For 12–17-year-olds, only the Pfizer-BioNTech COVID-19 vaccine is authorized and recommended for use.

[†] CDC recommendations allow a person to choose which vaccine booster product they receive (mix and match). Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most situations.

include severe allergic reactions. See additional information on vaccine side effects for <u>Pfizer-BioNTech</u>, <u>Moderna</u>, and <u>J&J</u>.

Since April 2021, FDA has investigated rare but severe side effects associated with the COVID-19 vaccines. The mRNA vaccines (Pfizer-BioNTech and Moderna) were found to have a suggested <u>increased</u> risk of myocarditis and pericarditis. The J&J vaccine was found to have a suggested increased risk of <u>thrombosis with</u> <u>thrombocytopenia syndrome</u> and <u>Guillain-Barré Syndrome</u>. All events were found to be uncommon, and the vaccines' benefits continue to outweigh the risks found.

Coadministration of Vaccine

Following an emergency Advisory Committee for Immunization Practices (ACIP) meeting on May 12, 2021, CDC revised vaccine administration guidance indicating that COVID-19 vaccines can be co-administered with other vaccines without regard to timing. Coadministration information is summarized in CDC's Interim Clinical Considerations guidance.

Variants

Update: The <u>Omicron variant</u> was first detected in the United States in December 2021 and quickly became the dominant variant. Like other variants, Omicron is comprised of a number of lineages and sublineages. Current COVID-19 vaccines to protect against severe illness, hospitalizations, and deaths from infection with the Omicron variant. However, breakthrough infections in people who are fully vaccinated can occur. People who are <u>up to date</u> with their COVID-19 vaccines and get COVID-19 are less likely to develop serious illness than those who are unvaccinated and get COVID-19. CDC and WHO continue to monitor other <u>variants of interest</u>, <u>concern</u>, and <u>high consequence</u>. Track COVID-19 variant proportions <u>here</u>.

CDC and ACIP Recommend mRNA Vaccines to Combat COVID-19

On Dec. 16, CDC <u>endorsed</u> ACIP's updated COVID-19 vaccine recommendations. ACIP unanimously voted to say mRNA vaccines are preferred over the use of the Johnson & Johnson vaccine for all persons 18 years and older in the United States.

Considerations for an Eight-Week Interval Between the First and Second Doses of a Primary mRNA Vaccine

Following a thorough evaluation of the latest <u>safety and effectiveness data</u>, CDC is providing <u>new information</u> to help healthcare providers recommend the optimal COVID-19 vaccination schedule based on the individual patient. This updated guidance is specific to the mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccine primary series and is only for some patients who are not yet vaccinated. Specifically, people ages 12-64 years old who are not moderately or severely immunocompromised—and particularly males ages 12-39 years—may benefit from getting their second mRNA COVID-19 vaccine dose eight weeks after their first dose, instead of after the FDA-approved or FDA-authorized three-week (Pfizer-BioNTech) or four-week (Moderna) interval.

Extending the time interval between primary mRNA COVID-19 vaccine doses from the FDA-approved or authorized three weeks (Pfizer-BioNTech) or four weeks (Moderna) to eight weeks may help increase how long protection lasts against COVID-19. It may also help lower the (small) risk of myocarditis (inflammation of the heart muscle) and pericarditis (swelling of tissue around the heart), which has been associated—mostly among adolescent and young adult males—with mRNA COVID-19 vaccination.

Population Specific Considerations

Pregnant and Lactating People

The American College of Obstetricians and Gynecologists, the Society for Maternal-Fetal Medicine, and CDC recommend that all pregnant and lactating people should be vaccinated against COVID-19 in response to growing evidence of safe and effective use of COVID-19 vaccines during pregnancy and breastfeeding. Safety monitoring systems from FDA and CDC have not identified any safety concerns among pregnant or lactating people. Additionally, completed data from animal studies show no issues. Pregnant and lactating people should discuss the risks and benefits with their provider.