

COVID-19 VACCINE COMPARISON CHART from The Medical Letter®

	FDA Approved for Use in the US		FDA Authorized in US for Emergency Use		Not Authorized in the US
	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
Name	<i>Comirnaty</i> (BNT162b2)	<i>Spikevax</i> (mRNA-1273)	Ad26.COVS.2.S	NVX-CoV2373	ChAdOx1 nCoV-19
Vaccine Type	mRNA	mRNA	Adenovirus vector	Recombinant nanoparticle, adjuvanted	Adenovirus vector
Age	Approval: ≥16 years old** Approval: 12-15 years old** EUA: 5-11 years old**, ^{91,93} EUA: 6 months-<5 years old	Approval: ≥18 years old EUA: 6-11 years old EUA: 6 months-5 years old	≥18 years old	≥18 years old ¹²¹ 12-17 years old (EUA updated 8/2022) ¹²²	≥18 years old
Primary Series Dosage	<p>≥12 yrs: 30 mcg given as 2 doses 3-8[†] weeks apart¹¹³⁻¹¹⁴</p> <p>5-11 yrs: 10 mcg given as 2 doses 3 weeks apart⁹¹</p> <p>6 months-<4 yrs: 3 mcg monovalent given at 0 and 3 weeks, followed by 1 bivalent dose given ≥8 weeks after dose 2¹²⁰</p> <p>Immunocompromised EUA: 3rd dose 28 days after the 2nd dose in ≥5 yrs*.^{62-64,109}</p>	<p>≥12 yrs: 100 mcg given as 2 doses 4-8[†] weeks apart^{113-114,120}</p> <p>6-11 yrs: 50 mcg given as 2 doses 4 weeks apart¹²⁰</p> <p>6 months-5 yrs: 25 mcg given as 2 doses 4 weeks apart¹²⁰</p> <p>Immunocompromised EUA: 3rd dose 28 days after the 2nd dose*.⁶²⁻⁶⁴</p>	<p>1 dose (0.5 mL; 5 x10¹⁰ virus particles)</p> <p>Immunocompromised: 1 dose Pfizer or Moderna (100 mcg) ≥4 weeks after 1st J&J vaccine</p> <p>▪ FDA limits use to only those who are not able or willing to receive an mRNA vaccine because of thrombocytopenia syndrome (TTS) risk¹⁰⁷</p>	<p>≥12 yrs: 2 doses (0.5 mL) 3 weeks apart</p> <p>Each 0.5-mL dose contains 5 mcg SARS-CoV-2 recombinant spike protein and 50 mcg Matrix-M adjuvant</p>	<p>2 doses (0.5 mL; 5 x10¹⁰ viral particles) 4-12 weeks apart</p>
Bivalent Booster (in US)	<ul style="list-style-type: none"> ▪ Contains mRNA component of original strain and common component of BA.4 and BA.5¹²⁴ ▪ 6 mos-4 yrs: 1 dose (3 mcg) if primary series was 3 monovalent doses ▪ ≥5-11 yrs: 1 dose (10 mcg) ▪ ≥12 yrs: 1 dose (30 mcg) ▪ Given ≥2 months after primary series or a previous booster dose 	<ul style="list-style-type: none"> ▪ Contains mRNA component of original strain and common component of BA.4 and BA.5¹²⁴ ▪ 6 mos-5 yrs: 1 dose (10 mcg) ▪ ≥6-11 yrs: 1 dose (25 mcg) ▪ ≥12 yrs: 1 dose (50 mcg) ▪ Given ≥2 months after primary series or a previous booster dose 	<ul style="list-style-type: none"> ▪ Eligible persons should receive a bivalent Pfizer/BioNTech or Moderna booster dose ≥2 months after primary series or previous booster dose 	<ul style="list-style-type: none"> ▪ Eligible persons should receive a bivalent Pfizer/BioNTech or Moderna booster dose ≥2 months after primary series 	-
Monovalent Booster (in US)	<ul style="list-style-type: none"> ▪ Monovalent booster no longer authorized for persons ≥5 years old; such patients who are eligible for a booster dose should receive the bivalent booster¹²⁴ 	<ul style="list-style-type: none"> ▪ Monovalent booster no longer authorized¹²⁴ 	<p>FDA EUA and CDC:^{81,87,88,97}</p> <ul style="list-style-type: none"> ▪ ≥2 months after primary J&J dose or after mRNA dose in immunocompromised ▪ CDC recommends preferential use of an mRNA vaccine over J&J vaccine¹⁰⁷ ▪ If J&J used, 1 dose (0.5 mL) ▪ anyone ≥18 years old who received the J&J primary dose 	<ul style="list-style-type: none"> ▪ Persons ≥18 years old who have not previously received a COVID-19 booster vaccine dose and who are unable to receive an mRNA vaccine, a Novavax monovalent booster dose may be given ≥6 months after a primary series 	-

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca	
Efficacy						
Overall	<ul style="list-style-type: none"> 95% (7 days after 2nd dose)¹; 91% (6 mos)⁵⁴ 	<ul style="list-style-type: none"> 94.1% (14 days after 2nd dose)²; 93.2% (~5.3 mos)⁵⁵ 	<ul style="list-style-type: none"> 66.1% (overall)^{3,4} 72.0% (US)^{3,4} Immune responses reported up to 8 months⁵⁰ 94% (booster ≥2 months after primary dose)⁷⁹ 	<ul style="list-style-type: none"> 90.4% (US overall; 7 days after 2nd dose)⁴⁰ 92.6% (against VOC)⁴⁰ 100% (against variants not of concern)⁴⁰ 89.7% (UK overall; 7 days after 2nd dose)^{6,40} 	<ul style="list-style-type: none"> 66.7% (overall; >14 days after 2nd dose)⁵ 82.4% (2nd dose ≥12 wks after 1st dose); 54.9% (2nd dose <6 wks after 1st dose)⁵ 76% (US overall; 15 days after 2nd dose)¹³ 	
In Elderly Persons	94.7% (≥65 yrs) ¹ ; >80% vs hosp. (≥75 yrs) ⁷¹ ; 74.7% ⁷⁴	86.4% (≥65 yrs) ² ; >80% vs hosp. (≥75 yrs) ⁷¹ ; 74.7% ⁷⁴	66.2% (≥60 yrs) ⁴	91.0% efficacy in “high-risk” (includes >65 yrs) ⁴⁰	Limited data	
In Adolescents (12-15, 12-17 years old)	100% ¹⁴ ; 93% (vs hosp in 12-18 yrs) ⁹⁶	100%; 96% ²⁶	-	Antibody response >young adults ¹²³ ; 78.3% ¹²³	-	
In Children (5-11, 6-11 years old)	90.7% (10 mcg) ⁸⁹ ; nAb similar to 16-25 yr olds ^{77,119}	antibody response similar to 18-25 yr olds ^{90,117,118}	-	-	-	
In Children (2-<5 or 6 years old)	Antibody response did not meet non-inferiority for 2 doses ¹⁰⁷ ; antibody response similar to 16-25 yr olds for 3 doses ¹¹⁹	36.8%; antibody response similar to 18-25 yr olds ^{117,118}	-	-	-	
In Children (6-23 months old)	Antibody response similar to older subgroups ¹¹⁹	50.6%; antibody response similar to 18-25 yr olds ^{117,118}	-	-	-	
In Severe Disease	90% ¹ ; 97% ⁵⁴ ; 84-86% ⁷² ; 88% (vs hosp) ⁷⁵ ; >86% ⁹⁹	100% ² ; 98.2% ⁵⁵ ; 84-86% ⁷² ; 93% (vs hosp) ⁷⁵ ; >86% ⁹⁹	85.4% ⁴ ; US: 87.6% ⁴ ; 71%, 81% ⁸⁰ (vs hosp) ⁷⁵ ; >86% ⁹⁹	100% ^{9,40}	100% ^{5,8}	
COVID-19 Death	100% ¹	100% ^{2,55}	100% ⁴	100% ⁹	100%	
Variants	Delta (India; B.1.617.2)	87.9% ³⁰ ; 79% ⁴² ; 64% ⁴³ ; 96% vs hosp. ³⁷ ; 87% ⁴⁴ ; 88% (30.7% 1 dose) ⁴⁹ ; 46% ⁵⁶ ; 39-84% ⁷¹ ; 75-95% vs hosp. ⁷¹ ; 53.1% ⁷⁴ ; 72.3% ⁹⁹	72% (1 dose) ⁴⁴ ; 76% ⁵⁶ ; 39-84% ⁷¹ ; 75-95% vs hosp. ⁷¹ ; 53.1% ⁷⁴ ; 77.8% ⁹⁹	78% ⁸⁰ ; 69.4% ⁹⁹ ; 1.6-fold lower nAb ⁴⁶ ; 5.4-fold lower nAb ⁴⁸	Data not available	59.8% ³⁰ ; 60% ⁴² ; 92% against hospitalization ³⁷ ; 67% (1 dose) ⁴⁴ ; 67.0% ⁴⁹
	Alpha (B.1.1.7; UK)	85% ²³ ; 89.5% ²⁵ ; 89% ⁴⁴ ; 93.7% (48.7% 1 dose) ⁴⁹ ; 91.3% ⁹⁹	92% ⁴⁴ ; 96.9% ⁹⁹ ; <i>in vitro</i> activity ^{11,31}	~60-75% ⁷ ; 86.6% ⁹⁹	86.3% ⁹	64% (1 dose) ⁴⁴ ; 74.6% ⁵ ; 70.4% ²² ; 74.5% ⁴⁹
	Beta (B.1.351; South Africa)	75.0% ²⁵ ; 84% ⁴⁴ ; 100% ⁵⁴	77% (1 dose) ⁴⁴ ; <i>in vitro</i> lower activity ^{11,31}	64.0% ⁴ ; 6.7-fold lower nAb	43.0% overall; 51.0% HIV-negative ⁹	48% (1 dose) ⁴⁴ ; 10.4% ¹²
	Gamma (P.1; Brazil)	84% ⁴⁴ ; <i>in vitro</i> activity ¹⁰	77% (1 dose) ⁴⁴ ; <i>in vitro</i> lower ^{11,31}	68.1% ⁴	Data not available	48% (1 dose) ⁴⁴ ; effective (prelim data)
	Iota (NY; B.1.526)	<i>In vitro</i> lower activity ²⁷	<i>In vitro</i> lower activity ^{27,31}	Data not available	Data not available	Data not available
	Epsilon (B.1.427/ B.1.429; CA)	<i>In vitro</i> lower activity ²⁸	<i>In vitro</i> lower activity ^{28,31}	Data not available	<i>In vitro</i> lower activity ²⁸	Data not available
	Omicron (B.1.1.529)	30%-40% (2 doses) ¹⁰⁴ ; 70%-80% (3 doses) ¹⁰⁴ ; 70% vs hosp; 90% vs hosp (3 doses) ^{100,103}	90% vs hosp (3 doses) ¹⁰⁰ ; lower nAb, increased with booster ^{106,108}	Data not available	Data not available	Titers dropped below detectable threshold ¹⁰⁵

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
Storage Requirements					
Transport and Storage	<p><u>Purple cap vials (≥12 yrs; must dilute):</u></p> <ul style="list-style-type: none"> -60 to -90°C Alt: -25 to -15°C x 2 wks <p><u>Gray cap vials (≥12 yrs; do not dilute):</u></p> <ul style="list-style-type: none"> -60 to -90°C (transport) <p><u>Orange cap vials (5-11 yrs; must dilute):</u></p> <ul style="list-style-type: none"> -60 to -90°C or -25 to -15°C (for transport only) <p><u>Maroon cap vials (6 months-<5 yrs; must dilute):</u></p> <ul style="list-style-type: none"> -60 to -90°C or -25 to -15°C (for transport only) 	<ul style="list-style-type: none"> -50 to -15°C Alt: 2-8°C x 12 hrs <p>Black border vials (≥12 yrs) Purple border vials (≥18 yrs booster) Light blue border (≥12 yrs and booster for ≥18 yrs) Teal & purple border vials (6-11 yrs) Magenta border vials (6 months-5 yrs)</p>	<ul style="list-style-type: none"> 2-8°C x 11 months³⁸ 	<ul style="list-style-type: none"> 2-8°C 	<ul style="list-style-type: none"> 2-8°C
Excursions at distribution	<p><u>Purple cap vials (≥12 yrs):</u></p> <ul style="list-style-type: none"> 2-8°C x 1 month 8-25°C x ≤2 hrs <p><u>Gray cap vials (≥12 yrs; do not dilute):</u></p> <ul style="list-style-type: none"> 2-8°C x 10 weeks 8-25°C x 12 hrs <p><u>Orange cap vials (5-11 yrs):</u></p> <ul style="list-style-type: none"> 2-8°C x 10 weeks 8-25°C x 12 hrs <p><u>Maroon cap vials (6 months-<5 yrs; must dilute):</u></p> <ul style="list-style-type: none"> 2-8°C x 10 weeks 8-25°C x 12 hrs 	<ul style="list-style-type: none"> 2-8°C x 30 days 8-25°C x 24 hrs <p>Black border vials (≥12 yrs) Purple border vials (≥18 yrs booster) Light blue border (≥12 yrs and booster for ≥18 yrs) Teal & purple border vials (6-11 yrs) Magenta border vials (6 months-5 yrs)</p>	<ul style="list-style-type: none"> 9-25°C x 12 hrs 	<ul style="list-style-type: none"> 2-8°C 	-
After Puncture/Dilution	<p><u>Purple cap vials (≥12 yrs; must dilute):</u></p> <ul style="list-style-type: none"> 2-25°C x 6 hrs <p><u>Gray cap vials (≥12 yrs; do not dilute):</u></p> <ul style="list-style-type: none"> 2-25°C x 12 hrs <p><u>Orange cap vials (5-11 yrs; must dilute):</u></p> <ul style="list-style-type: none"> 2-25°C x 12 hrs <p><u>Maroon cap vials (6 months-<5 yrs; must dilute):</u></p> <ul style="list-style-type: none"> 2-25°C x 12 hrs 	<ul style="list-style-type: none"> 2-25°C x 12 hrs <p>Black border vials (≥12 yrs) Purple border vials (≥18 yrs booster) Light blue border (≥12 yrs and booster for ≥18 yrs) Teal & purple border vials (6-11 yrs) Magenta border vials (6 months-5 yrs)</p>	<ul style="list-style-type: none"> 2-8°C x 6 hrs 8-25°C x 2 hrs 	<ul style="list-style-type: none"> 2-25°C x 6 hrs 	<ul style="list-style-type: none"> 2-8°C x 48 hrs 9-30°C x 6 hrs

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Some Post-Authorization Reports						
Efficacy	<p><u>Pooled Data with Both mRNA Vaccines:</u></p> <ul style="list-style-type: none"> 91% efficacy (overall for both mRNA vaccines under real-world conditions; ≥14 days after 2nd dose); 81% efficacy (≥14 days after dose 1 to 13 days after dose 2); shorter/milder illness; may reduce transmission^{15,36} 96% (hospitalization) and 98.7% (death)³² 94% (hospitalization) in ≥65 years old fully vaccinated (64% in partially vaccinated)³⁵ In persons previously infected with COVID-19, the likelihood of reinfection was significantly higher in unvaccinated persons compared to those who were vaccinated (OR = 2.34; 95% CI 1.58-3.47)⁵³ Breakthrough cases in UK study reported in 0.5% of people with 1 vaccine dose (BNT162b2, mRNA-1283, or ChAdOx1 nCoV-19) and 0.2% of people with 2 doses; vaccination associated with reduced odds of COVID symptoms ≥28 days⁷³ Efficacy vs hospitalization: 86% 2-12 weeks after 2nd dose; 84% 13-24 weeks after 2nd dose (MMWR)⁷¹ Odds of confirmed COVID-19 5.49-fold higher in unvaccinated persons with a history of SARS-CoV-2 infection than in vaccinated persons with no prior infection⁹² In U.S. veterans, risk of COVID-19 outcomes was low after mRNA vaccination; risks were lower with Moderna vaccine than with Pfizer/BioNTech vaccine⁹⁸ <p><u>Data with Pfizer/BioNTech Vaccine:</u></p> <ul style="list-style-type: none"> 46% after 1st dose and 92% after 2nd dose (Israel)²⁴ Single dose ~ 80% effective against hospital admission in persons >70 years old⁷ Study of breakthrough infections in Israel reported 39 infections/1497 fully vaccinated health care workers; most mild or asymptomatic; symptoms >6 weeks in 19%⁵² Booster (3rd) dose in persons ≥60 years old who had been fully vaccinated for at least 5 months decreased relative risk of confirmed infection by 11-fold and relative risk of severe illness by >10-fold (Israel)⁶⁷ Retrospective cohort study reported lower effectiveness of Pfizer/BioNTech vaccine against infection at 5 months after vaccination (47%) compared to during the 1st month after (88%); effectiveness against hospitalization was not significantly reduced (88% at 5 months vs 87% within 1 month); for Delta effectiveness against infection was 93% within the 1st month and 53% at 4 months; effectiveness against hospitalization for Delta was 93% up to 6 months⁸²5-11 years old: antibody titers noninferior to 16-25 year-olds, efficacy 90.7% in descriptive analysis (16 cases placebo vs 3 cases vaccine), no severe cases reported, adverse effects similar to 16-25 years old (most local and systemic reactogenicity; more severe after dose 2); lymphadenopathy reported, no anaphylaxis reported, no myocarditis/pericarditis reported, but sample size small In a prospective, longitudinal, cohort study, the secondary attack rate in household contacts exposed to the delta variant was 25% (95% CI 18-33) in fully vaccinated persons and 38% in unvaccinated persons (95%CI 24-53); peak viral load was similar between unvaccinated and vaccinated persons; rate of viral load decline was faster in vaccinated persons⁹⁴ 					<ul style="list-style-type: none"> Single dose ~73% effective against symptomatic COVID-19 and ~ 80% effective against hospital admission in persons >70 years old⁷ In a case control study in the UK, breakthrough COVID-19 cases were reported in 0.5% of people who had received 1 vaccine dose (BNT162b2, mRNA-1283, or ChAdOx1 nCoV-19) and 0.2% of people who received 2 vaccine doses; vaccination was associated with reduced odds of COVID symptoms ≥28 days In a prospective, longitudinal, cohort study, the secondary attack rate in household contacts exposed to the delta variant was 25% (95% CI 18-33) in fully vaccinated persons and 38% in unvaccinated persons (95%CI 24-53); peak viral load was similar between unvaccinated and vaccinated persons; rate of viral load decline was faster in vaccinated persons⁹⁴

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Some Post-Authorization Reports (continued)					
Efficacy (continued)	<p>Data with Janssen/J&J Vaccine:</p> <ul style="list-style-type: none"> ▪ Booster: booster given 2 months after primary dose was 94% effective against moderate to severe disease in the US (75% globally); 100% efficacy vs severe/critical disease; antibodies increased 4-fold when booster given 2 months after initial vaccination and 12-fold when given 6 months after the 1st dose⁷⁹ ▪ Real-world, cohort study reported estimated vaccine efficacy 79% vs COVID-19 infection, 81% vs hospitalization, 78% vs Delta, and 64% in immunocompromised⁸⁰ <p>Pooled Data All Available Vaccines:</p> <ul style="list-style-type: none"> ▪ CDC evaluation of data from the HEROES-RECOVER trial that included all available COVID-19 vaccines in the US reported vaccine efficacy of 66% during a period when Delta variant was predominant⁶⁶ ▪ Vaccine Mixing: phase 1/2 trial in 458 persons vaccinated with a different booster than primary series (J&J, Moderna, Pfizer/BioNTech)⁸⁶ <ul style="list-style-type: none"> • Antibody levels increased (4.6-56-fold) in all groups after booster of different vaccine • Neutralizing antibody titers increased 4-20-fold with homologous boost combinations vs 6-76-fold with heterologous boost combinations • Neutralizing antibody titers in J&J primary dose recipients increased 76-fold after Moderna booster, 35-fold after Pfizer booster, and 4-fold after J&J booster • Serum neutralization levels at baseline (before booster) were lower for Pfizer/BioNTech (3-fold) and J&J (10-fold) recipients than for Moderna recipients <p>Reactogenicity and adverse events similar across all groups</p> <p>CDC report (all vaccines available in the US)²¹ October 4th Report (CDC now monitoring only hospitalized or fatal cases instead of all cases)</p> <ul style="list-style-type: none"> ▪ 30,177 hospitalized or fatal vaccine breakthrough cases out of >185 million fully vaccinated ▪ 5660 (86%) deaths and 15,792 hospitalizations (67%) were ≥65 years old ▪ 2902 (44%) deaths and 11,474 (49%) hospitalizations in women ▪ 968 (15%) deaths and 3483 (15%) hospitalizations as symptomatic or not COVID-related 				
Some Post-Authorization Reports (continued)					
Safety	<ul style="list-style-type: none"> ▪ Greater systemic reactogenicity (feverishness, chills, fatigue, headache, joint pain, malaise, and muscle ache) was reported following a mixed vaccination schedule with the AstraZeneca and Pfizer/BioNTech vaccines compared to a homologous schedule²⁹ 	<ul style="list-style-type: none"> ▪ Myocarditis after mRNA vaccination^{39,41,51} <ul style="list-style-type: none"> ▪ Warning in FDA labeling ▪ ACIP states vaccine benefit outweighs risk⁴⁷ ▪ Most cases after dose 2 ▪ Most cases in persons 16-24 years old ▪ Most cases in males ▪ Median time to onset 2 days after dose 2 ▪ Most cases were mild; no deaths occurred 	<ul style="list-style-type: none"> ▪ CDC/FDA reviewed cases of thrombosis-thrombocytopenia syndrome (TTS) and recommend use of the vaccine resume in the US w/o age/gender restriction¹⁸ <ul style="list-style-type: none"> ▪ risk highest in women 18-49 years old ▪ onset mean of 8 days post-vaccination (range 6-15 days) ▪ vaccine labeling now contains information about the risk^{4,19} 	<ul style="list-style-type: none"> ▪ Injection-site pain, redness and swelling, fatigue, muscle pain, headache, joint pain, nausea, vomiting, fever ▪ Increased risk of myocarditis and pericarditis; symptoms began within 10 days of vaccination in most cases 	<ul style="list-style-type: none"> ▪ European Medicines Agency (EMA) reports possible link between vaccine and cases of CVST and splanchnic vein thrombosis with thrombocytopenia²⁰ ▪ Some countries have suspended or limited use of the vaccine

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
Some Post-Authorization Reports (continued)					
Safety (continued)	<ul style="list-style-type: none"> ■ Myocarditis after mRNA vaccination^{39,41,51} <ul style="list-style-type: none"> ● FDA warning in labeling ● ACIP: benefits outweigh risk of myocarditis⁴⁷ ● Most cases occurred after 2nd dose ● Most cases in persons 16-24 years old ● Most cases in males ● Median time to onset 2 days after dose 2 ● Most cases were mild; no deaths occurred ■ CDC estimates for every 1 million males 12-29 years old who receive mRNA vaccine, 560 hospitalizations due to COVID-19 would be prevented and 39-47 cases of myocarditis would occur ■ Cases of herpes zoster reactivation in patients with autoimmune inflammatory reumatic diseases¹⁶ ■ FDA reviewing adverse events of interest in persons ≥65 years old (pulmonary embolism, acute MI, immune thrombocytopenia, disseminated intravascular coagulation) ■ No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]); some confidence intervals were wide^{68,69} 	<ul style="list-style-type: none"> ■ CDC estimates for every 1 million males 12-29 years old who receive mRNA vaccine, 560 hospitalizations due to COVID-19 would be prevented and 39-47 cases of myocarditis would occur ■ Delayed cutaneous reactions¹⁷ ■ CDC, ACOG and SMFM state vaccination against COVID-19 is safe during pregnancy and they recommend COVID-19 vaccination for all pregnant people (and trying or planning to become pregnant in the future) and breastfeeding people⁵⁸⁻⁶¹ ■ No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]); some confidence intervals were wide^{68,69} 	<ul style="list-style-type: none"> ■ Case of death due to TTS reported in a woman in her late 30's who received the J&J vaccine⁸³ ■ Warning added to labeling about increased risk of Guillain-Barré syndrome (GBS) <ul style="list-style-type: none"> ■ 100 cases reported after 12.8 million doses ■ 95 required hospitalization; 1 death ■ Persons >50 years old and men appear to be at greatest risk ■ Most cases occurred within 42 days after vaccination ■ CDC and ACOG state that women <50 years old should be aware of the risk of thrombosis with thrombocytopenia syndrome (TTS) associated with the J&J/Janssen vaccine and that FDA-authorized mRNA vaccines are available that have not been associated with this risk^{60,61} 		<ul style="list-style-type: none"> ■ In a prospective cohort study that identified 170 definite and 50 probable cases of vaccine induced thrombocytopenia and thrombosis, overall mortality was 22% and was highest in among patients with a low platelet count and intracranial hemorrhage⁵⁷ ■ Greater systemic reactogenicity (feverishness, chills, fatigue, headache, joint pain, malaise, and muscle ache) was reported following a mixed vaccination schedule with the AstraZeneca and Pfizer/BioNTech vaccines compared to a homologous schedule²⁹

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
Some Post-Authorization Reports (continued)					
Safety (continued)	<ul style="list-style-type: none"> ■ CDC, ACOG and SMFM state vaccination against COVID-19 is safe during pregnancy and they recommend COVID-19 vaccination for all pregnant people (and people who are trying get pregnant or plan to become pregnant in the future) and breastfeeding people⁵⁸⁻⁶¹ ■ Booster safety data (n=306) - reactogenicity not increased vs dose 2, lymphadenopathy more frequent after booster vs after primary series (5.2% vs 0.4%), no deaths, vaccine-related serious adverse events, myocarditis, pericarditis, anaphylaxis, appendicitis, or Bell's palsy reported⁷⁶ ■ Based on reports to v-safe, adverse reactions after 3rd dose were similar to those after 2nd dose⁸⁴ ■ In a large study (2.4 million vaccinated in Israel), vaccination associated with an increased risk of myocarditis (2.7 events/100,000 persons), lymphadenopathy (78.4 events), herpes zoster (15.8 events), and appendicitis (5.0 events); SARS-CoV-2 infection associated with an excess myocarditis risk (11.0 events/100,000 persons) and other adverse events not associated with 				

vaccine use; in a subsequent analysis stratified by age and sex, the risk of myocarditis after vaccination in males 16-39 years old was 8.2 excess events/100,000 persons (95% CI 2.82-14.35) and the risk after SARS-CoV-2 infection was 11.54 excess events/100,000 persons (95% CI 2.48-22.55)^{70,95}

EUA = emergency use authorization; hosp = hospitalization; nAb= neutralizing antibodies; VOC = variants of concern

* CDC recommends a 3rd dose for moderately to severely immunocompromised people, including people who have been receiving active cancer treatment for solid tumors or hematologic malignancies, received an organ transplant and are taking immunosuppressants, received a stem cell transplant within the last 2 years or are taking immunosuppressants, those with moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome), have advanced or untreated HIV infection, or are receiving active treatment with high-dose corticosteroids (≥ 20 mg prednisone/day or equivalent), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>; <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-13.html>)^{63,64}

** FDA approved for individuals ≥16 years old; the vaccine is available for persons 12-15 years old and 5-11 years old through an emergency use authorization (EUA)

† An 8-week interval may be optimal for certain persons ≥12 years old, especially males 12-39 years old. A standard 3- (Pfizer/BioNTech) or 4- (Moderna) week interval between the first two doses should still be used in adults ≥65 years old, persons who are moderately or severely immunocompromised, and other persons who require more rapid protection because of high levels of community spread of SARS-CoV-2 infection or a high risk of severe COVID-19.¹¹³⁻¹¹⁴

For more information see [Treatments Considered for COVID-19](#)

1. FP Polack et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med 2020; 383:2603.
2. LR Baden et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. N Engl J Med 2021; 384: 403.
3. J Sadoff et al. Safety and efficacy of single-dose Ad26.COV2.S vaccine against Covid-19. N Engl J Med 2021; 384:2187.
4. FDA. Fact sheet for healthcare providers administering vaccine. Emergency Use Authorization (EUA) of the Janssen COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19). Available at: <https://www.fda.gov/media/146304/download>. Accessed April 26, 2021.
5. M Voysey et al. Single dose administration, and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV19 (AZD1222) vaccine: a pooled analysis of four randomised trials. Lancet 2021; 397:881.
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