

# 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
<b>Name</b>	<i>Comirnaty</i> (BNT162b2)	<i>Spikevax</i> (mRNA-1273)	Ad26.COVS.2.S	NVX-CoV2373	ChAdOx1 nCoV-19
<b>Vaccine Type</b>	mRNA	mRNA	Adenovirus vector	Recombinant nanoparticle, adjuvanted	Adenovirus vector
<b>Age</b>	Approval: ≥16 years old** Approval: 12-15 years old** EUA: 5-11 years old**, <sup>91,93</sup> 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 <sup>121</sup> 12-17 years old (EUA updated 8/2022) <sup>122</sup>	≥18 years old
<b>Primary Series Dosage</b>	<p>≥12 yrs: 30 mcg given as 2 doses 3-8<sup>†</sup> weeks apart<sup>113-114</sup></p> <p>5-11 yrs: 10 mcg given as 2 doses 3 weeks apart<sup>91</sup></p> <p>6 months-&lt;4 yrs: 3 mcg monovalent given at 0 and 3 weeks, followed by 1 bivalent dose given ≥8 weeks after dose 2<sup>120</sup></p> <p>Immunocompromised EUA: 3<sup>rd</sup> dose 28 days after the 2<sup>nd</sup> dose in ≥5 yrs*.<sup>62-64,109</sup></p>	<p>≥12 yrs: 100 mcg given as 2 doses 4-8<sup>†</sup> weeks apart<sup>113-114,120</sup></p> <p>6-11 yrs: 50 mcg given as 2 doses 4 weeks apart<sup>120</sup></p> <p>6 months-5 yrs: 25 mcg given as 2 doses 4 weeks apart<sup>120</sup></p> <p>Immunocompromised EUA: 3<sup>rd</sup> dose 28 days after the 2<sup>nd</sup> dose*.<sup>62-64</sup></p>	<p>1 dose (0.5 mL; 5 x10<sup>10</sup> virus particles)</p> <p>Immunocompromised: 1 dose Pfizer or Moderna (100 mcg) ≥4 weeks after 1st J&amp;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) risk<sup>107</sup></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 x10<sup>10</sup> viral particles) 4-12 weeks apart</p>
<b>Bivalent Booster (in US)</b>	<ul style="list-style-type: none"> <li>▪ Contains mRNA component of original strain and common component of BA.4 and BA.5<sup>124</sup></li> <li>▪ <b>6 mos-4 yrs: 1 dose (3 mcg) if primary series was 3 monovalent doses</b></li> <li>▪ <b>≥5-11 yrs: 1 dose (10 mcg)</b></li> <li>▪ <b>≥12 yrs: 1 dose (30 mcg)</b></li> <li>▪ Given ≥2 months after primary series or a previous booster dose</li> </ul>	<ul style="list-style-type: none"> <li>▪ Contains mRNA component of original strain and common component of BA.4 and BA.5<sup>124</sup></li> <li>▪ <b>6 mos-5 yrs: 1 dose (10 mcg)</b></li> <li>▪ <b>≥6-11 yrs: 1 dose (25 mcg)</b></li> <li>▪ <b>≥12 yrs: 1 dose (50 mcg)</b></li> <li>▪ Given ≥2 months after primary series or a previous booster dose</li> </ul>	<ul style="list-style-type: none"> <li>▪ Eligible persons should receive a bivalent Pfizer/BioNTech or Moderna booster dose ≥2 months after primary series or previous booster dose</li> </ul>	<ul style="list-style-type: none"> <li>▪ Eligible persons should receive a bivalent Pfizer/BioNTech or Moderna booster dose ≥2 months after primary series</li> </ul>	-
<b>Monovalent Booster (in US)</b>	<ul style="list-style-type: none"> <li>▪ Monovalent booster no longer authorized for persons ≥5 years old; such patients who are eligible for a booster dose should receive the bivalent booster<sup>124</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ Monovalent booster no longer authorized<sup>124</sup></li> </ul>	<p>FDA EUA and CDC:<sup>81,87,88,97</sup></p> <ul style="list-style-type: none"> <li>▪ ≥2 months after primary J&amp;J dose or after mRNA dose in immunocompromised</li> <li>▪ CDC recommends preferential use of an mRNA vaccine over J&amp;J vaccine<sup>107</sup></li> <li>▪ If J&amp;J used, 1 dose (0.5 mL)</li> <li>▪ anyone ≥18 years old who received the J&amp;J primary dose</li> </ul>	<ul style="list-style-type: none"> <li>▪ 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</li> </ul>	-

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca	
<b>Efficacy</b>						
<b>Overall</b>	<ul style="list-style-type: none"> <li>95% (7 days after 2<sup>nd</sup> dose)<sup>1</sup>; 91% (6 mos)<sup>54</sup></li> </ul>	<ul style="list-style-type: none"> <li>94.1% (14 days after 2<sup>nd</sup> dose)<sup>2</sup>; 93.2% (~5.3 mos)<sup>55</sup></li> </ul>	<ul style="list-style-type: none"> <li>66.1% (overall)<sup>3,4</sup></li> <li>72.0% (US)<sup>3,4</sup></li> <li>Immune responses reported up to 8 months<sup>50</sup></li> <li>94% (booster ≥2 months after primary dose)<sup>79</sup></li> </ul>	<ul style="list-style-type: none"> <li>90.4% (US overall; 7 days after 2<sup>nd</sup> dose)<sup>40</sup></li> <li>92.6% (against VOC)<sup>40</sup></li> <li>100% (against variants not of concern)<sup>40</sup></li> <li>89.7% (UK overall; 7 days after 2<sup>nd</sup> dose)<sup>6,40</sup></li> </ul>	<ul style="list-style-type: none"> <li>66.7% (overall; &gt;14 days after 2<sup>nd</sup> dose)<sup>5</sup></li> <li>82.4% (2<sup>nd</sup> dose ≥12 wks after 1<sup>st</sup> dose); 54.9% (2<sup>nd</sup> dose &lt;6 wks after 1<sup>st</sup> dose)<sup>5</sup></li> <li>76% (US overall; 15 days after 2<sup>nd</sup> dose)<sup>13</sup></li> </ul>	
<b>In Elderly Persons</b>	94.7% (≥65 yrs) <sup>1</sup> ; >80% vs hosp. (≥75 yrs) <sup>71</sup> ; 74.7% <sup>74</sup>	86.4% (≥65 yrs) <sup>2</sup> ; >80% vs hosp. (≥75 yrs) <sup>71</sup> ; 74.7% <sup>74</sup>	66.2% (≥60 yrs) <sup>4</sup>	91.0% efficacy in “high-risk” (includes >65 yrs) <sup>40</sup>	Limited data	
<b>In Adolescents (12-15, 12-17 years old)</b>	100% <sup>14</sup> ; 93% (vs hosp in 12-18 yrs) <sup>96</sup>	100%; 96% <sup>26</sup>	-	Antibody response >young adults <sup>123</sup> ; 78.3% <sup>123</sup>	-	
<b>In Children (5-11, 6-11 years old)</b>	90.7% (10 mcg) <sup>89</sup> ; nAb similar to 16-25 yr olds <sup>77,119</sup>	antibody response similar to 18-25 yr olds <sup>90,117,118</sup>	-	-	-	
<b>In Children (2-&lt;5 or 6 years old)</b>	Antibody response did not meet non-inferiority for 2 doses <sup>107</sup> ; antibody response similar to 16-25 yr olds for 3 doses <sup>119</sup>	36.8%; antibody response similar to 18-25 yr olds <sup>117,118</sup>	-	-	-	
<b>In Children (6-23 months old)</b>	Antibody response similar to older subgroups <sup>119</sup>	50.6%; antibody response similar to 18-25 yr olds <sup>117,118</sup>	-	-	-	
<b>In Severe Disease</b>	90% <sup>1</sup> ; 97% <sup>54</sup> ; 84-86% <sup>72</sup> ; 88% (vs hosp) <sup>75</sup> ; >86% <sup>99</sup>	100% <sup>2</sup> ; 98.2% <sup>55</sup> ; 84-86% <sup>72</sup> ; 93% (vs hosp) <sup>75</sup> ; >86% <sup>99</sup>	85.4% <sup>4</sup> ; US: 87.6% <sup>4</sup> ; 71%, 81% <sup>80</sup> (vs hosp) <sup>75</sup> ; >86% <sup>99</sup>	100% <sup>9,40</sup>	100% <sup>5,8</sup>	
<b>COVID-19 Death</b>	100% <sup>1</sup>	100% <sup>2,55</sup>	100% <sup>4</sup>	100% <sup>9</sup>	100%	
<b>Variants</b>	<b>Delta (India; B.1.617.2)</b>	87.9% <sup>30</sup> ; 79% <sup>42</sup> ; 64% <sup>43</sup> ; 96% vs hosp. <sup>37</sup> ; 87% <sup>44</sup> ; 88% (30.7% 1 dose) <sup>49</sup> ; 46% <sup>56</sup> ; 39-84% <sup>71</sup> ; 75-95% vs hosp. <sup>71</sup> ; 53.1% <sup>74</sup> ; 72.3% <sup>99</sup>	72% (1 dose) <sup>44</sup> ; 76% <sup>56</sup> ; 39-84% <sup>71</sup> ; 75-95% vs hosp. <sup>71</sup> ; 53.1% <sup>74</sup> ; 77.8% <sup>99</sup>	78% <sup>80</sup> ; 69.4% <sup>99</sup> ; 1.6-fold lower nAb <sup>46</sup> ; 5.4-fold lower nAb <sup>48</sup>	Data not available	59.8% <sup>30</sup> ; 60% <sup>42</sup> ; 92% against hospitalization <sup>37</sup> ; 67% (1 dose) <sup>44</sup> ; 67.0% <sup>49</sup>
	<b>Alpha (B.1.1.7; UK)</b>	85% <sup>23</sup> ; 89.5% <sup>25</sup> ; 89% <sup>44</sup> ; 93.7% (48.7% 1 dose) <sup>49</sup> ; 91.3% <sup>99</sup>	92% <sup>44</sup> ; 96.9% <sup>99</sup> ; <i>in vitro</i> activity <sup>11,31</sup>	~60-75% <sup>7</sup> ; 86.6% <sup>99</sup>	86.3% <sup>9</sup>	64% (1 dose) <sup>44</sup> ; 74.6% <sup>5</sup> ; 70.4% <sup>22</sup> ; 74.5% <sup>49</sup>
	<b>Beta (B.1.351; South Africa)</b>	75.0% <sup>25</sup> ; 84% <sup>44</sup> ; 100% <sup>54</sup>	77% (1 dose) <sup>44</sup> ; <i>in vitro</i> lower activity <sup>11,31</sup>	64.0% <sup>4</sup> ; 6.7-fold lower nAb	43.0% overall; 51.0% HIV-negative <sup>9</sup>	48% (1 dose) <sup>44</sup> ; 10.4% <sup>12</sup>
	<b>Gamma (P.1; Brazil)</b>	84% <sup>44</sup> ; <i>in vitro</i> activity <sup>10</sup>	77% (1 dose) <sup>44</sup> ; <i>in vitro</i> lower <sup>11,31</sup>	68.1% <sup>4</sup>	Data not available	48% (1 dose) <sup>44</sup> ; effective (prelim data)
	<b>Iota (NY; B.1.526)</b>	<i>In vitro</i> lower activity <sup>27</sup>	<i>In vitro</i> lower activity <sup>27,31</sup>	Data not available	Data not available	Data not available
	<b>Epsilon (B.1.427/ B.1.429; CA)</b>	<i>In vitro</i> lower activity <sup>28</sup>	<i>In vitro</i> lower activity <sup>28,31</sup>	Data not available	<i>In vitro</i> lower activity <sup>28</sup>	Data not available
	<b>Omicron (B.1.1.529)</b>	30%-40% (2 doses) <sup>104</sup> ; 70%-80% (3 doses) <sup>104</sup> ; 70% vs hosp; 90% vs hosp (3 doses) <sup>100,103</sup>	90% vs hosp (3 doses) <sup>100</sup> ; lower nAb, increased with booster <sup>106,108</sup>	Data not available	Data not available	Titers dropped below detectable threshold <sup>105</sup>

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
<b>Storage Requirements</b>					
<b>Transport and Storage</b>	<p><u>Purple cap vials (≥12 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>-60 to -90°C</li> <li>Alt: -25 to -15°C x 2 wks</li> </ul> <p><u>Gray cap vials (≥12 yrs; do not dilute):</u></p> <ul style="list-style-type: none"> <li>-60 to -90°C (transport)</li> </ul> <p><u>Orange cap vials (5-11 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>-60 to -90°C or -25 to -15°C (for transport only)</li> </ul> <p><u>Maroon cap vials (6 months-&lt;5 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>-60 to -90°C or -25 to -15°C (for transport only)</li> </ul>	<ul style="list-style-type: none"> <li>-50 to -15°C</li> <li>Alt: 2-8°C x 12 hrs</li> </ul> <p>Black border vials (≥12 yrs) Purple border vials (≥18 yrs booster) Light blue border (≥12 yrs and booster for ≥18 yrs) Teal &amp; purple border vials (6-11 yrs) Magenta border vials (6 months-5 yrs)</p>	<ul style="list-style-type: none"> <li>2-8°C x 11 months<sup>38</sup></li> </ul>	<ul style="list-style-type: none"> <li>2-8°C</li> </ul>	<ul style="list-style-type: none"> <li>2-8°C</li> </ul>
<b>Excursions at distribution</b>	<p><u>Purple cap vials (≥12 yrs):</u></p> <ul style="list-style-type: none"> <li>2-8°C x 1 month</li> <li>8-25°C x ≤2 hrs</li> </ul> <p><u>Gray cap vials (≥12 yrs; do not dilute):</u></p> <ul style="list-style-type: none"> <li>2-8°C x 10 weeks</li> <li>8-25°C x 12 hrs</li> </ul> <p><u>Orange cap vials (5-11 yrs):</u></p> <ul style="list-style-type: none"> <li>2-8°C x 10 weeks</li> <li>8-25°C x 12 hrs</li> </ul> <p><u>Maroon cap vials (6 months-&lt;5 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>2-8°C x 10 weeks</li> <li>8-25°C x 12 hrs</li> </ul>	<ul style="list-style-type: none"> <li>2-8°C x 30 days</li> <li>8-25°C x 24 hrs</li> </ul> <p>Black border vials (≥12 yrs) Purple border vials (≥18 yrs booster) Light blue border (≥12 yrs and booster for ≥18 yrs) Teal &amp; purple border vials (6-11 yrs) Magenta border vials (6 months-5 yrs)</p>	<ul style="list-style-type: none"> <li>9-25°C x 12 hrs</li> </ul>	<ul style="list-style-type: none"> <li>2-8°C</li> </ul>	-
<b>After Puncture/Dilution</b>	<p><u>Purple cap vials (≥12 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>2-25°C x 6 hrs</li> </ul> <p><u>Gray cap vials (≥12 yrs; do not dilute):</u></p> <ul style="list-style-type: none"> <li>2-25°C x 12 hrs</li> </ul> <p><u>Orange cap vials (5-11 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>2-25°C x 12 hrs</li> </ul> <p><u>Maroon cap vials (6 months-&lt;5 yrs; must dilute):</u></p> <ul style="list-style-type: none"> <li>2-25°C x 12 hrs</li> </ul>	<ul style="list-style-type: none"> <li>2-25°C x 12 hrs</li> </ul> <p>Black border vials (≥12 yrs) Purple border vials (≥18 yrs booster) Light blue border (≥12 yrs and booster for ≥18 yrs) Teal &amp; purple border vials (6-11 yrs) Magenta border vials (6 months-5 yrs)</p>	<ul style="list-style-type: none"> <li>2-8°C x 6 hrs</li> <li>8-25°C x 2 hrs</li> </ul>	<ul style="list-style-type: none"> <li>2-25°C x 6 hrs</li> </ul>	<ul style="list-style-type: none"> <li>2-8°C x 48 hrs</li> <li>9-30°C x 6 hrs</li> </ul>

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca	
<b>Some Post-Authorization Reports</b>						
<b>Efficacy</b>	<p><b><u>Pooled Data with Both mRNA Vaccines:</u></b></p> <ul style="list-style-type: none"> <li>91% efficacy (overall for both mRNA vaccines under real-world conditions; ≥14 days after 2<sup>nd</sup> dose); 81% efficacy (≥14 days after dose 1 to 13 days after dose 2); shorter/milder illness; may reduce transmission<sup>15,36</sup></li> <li>96% (hospitalization) and 98.7% (death)<sup>32</sup></li> <li>94% (hospitalization) in ≥65 years old fully vaccinated (64% in partially vaccinated)<sup>35</sup></li> <li>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)<sup>53</sup></li> <li>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 days<sup>73</sup></li> <li>Efficacy vs hospitalization: 86% 2-12 weeks after 2<sup>nd</sup> dose; 84% 13-24 weeks after 2<sup>nd</sup> dose (MMWR)<sup>71</sup></li> <li>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 infection<sup>92</sup></li> <li>In U.S. veterans, risk of COVID-19 outcomes was low after mRNA vaccination; risks were lower with Moderna vaccine than with Pfizer/BioNTech vaccine<sup>98</sup></li> </ul> <p><b><u>Data with Pfizer/BioNTech Vaccine:</u></b></p> <ul style="list-style-type: none"> <li>46% after 1<sup>st</sup> dose and 92% after 2<sup>nd</sup> dose (Israel)<sup>24</sup></li> <li>Single dose ~ 80% effective against hospital admission in persons &gt;70 years old<sup>7</sup></li> <li>Study of breakthrough infections in Israel reported 39 infections/1497 fully vaccinated health care workers; most mild or asymptomatic; symptoms &gt;6 weeks in 19%<sup>52</sup></li> <li><b>Booster</b> (3<sup>rd</sup>) 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 &gt;10-fold (Israel)<sup>67</sup></li> <li>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 1<sup>st</sup> month and 53% at 4 months; effectiveness against hospitalization for Delta was 93% up to 6 months<sup>82</sup><b>5-11 years old:</b> 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</li> <li>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 persons<sup>94</sup></li> </ul>					<ul style="list-style-type: none"> <li>Single dose ~73% effective against symptomatic COVID-19 and ~ 80% effective against hospital admission in persons &gt;70 years old<sup>7</sup></li> <li>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</li> <li>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 persons<sup>94</sup></li> </ul>

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
<b>Some Post-Authorization Reports (continued)</b>					
<b>Efficacy (continued)</b>	<p><b>Data with Janssen/J&amp;J Vaccine:</b></p> <ul style="list-style-type: none"> <li>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 1<sup>st</sup> dose<sup>79</sup></li> <li>Real-world, cohort study reported estimated vaccine efficacy 79% vs COVID-19 infection, 81% vs hospitalization, 78% vs Delta, and 64% in immunocompromised<sup>80</sup></li> </ul> <p><b>Pooled Data All Available Vaccines:</b></p> <ul style="list-style-type: none"> <li>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 predominant<sup>66</sup></li> <li>Vaccine Mixing: phase 1/2 trial in 458 persons vaccinated with a different booster than primary series (J&amp;J, Moderna, Pfizer/BioNTech)<sup>86</sup> <ul style="list-style-type: none"> <li>Antibody levels increased (4.6-56-fold) in all groups after booster of different vaccine</li> <li>Neutralizing antibody titers increased 4-20-fold with homologous boost combinations vs 6-76-fold with heterologous boost combinations</li> <li>Neutralizing antibody titers in J&amp;J primary dose recipients increased 76-fold after Moderna booster, 35-fold after Pfizer booster, and 4-fold after J&amp;J booster</li> <li>Serum neutralization levels at baseline (before booster) were lower for Pfizer/BioNTech (3-fold) and J&amp;J (10-fold) recipients than for Moderna recipients</li> </ul> </li> </ul> <p>Reactogenicity and adverse events similar across all groups</p> <p><b>CDC report (all vaccines available in the US)<sup>21</sup> October 4th Report</b> (CDC now monitoring only hospitalized or fatal cases instead of all cases)</p> <ul style="list-style-type: none"> <li>30,177 hospitalized or fatal vaccine breakthrough cases out of &gt;185 million fully vaccinated</li> <li>5660 (86%) deaths and 15,792 hospitalizations (67%) were ≥65 years old</li> <li>2902 (44%) deaths and 11,474 (49%) hospitalizations in women</li> <li>968 (15%) deaths and 3483 (15%) hospitalizations as symptomatic or not COVID-related</li> </ul>				
<b>Some Post-Authorization Reports (continued)</b>					
<b>Safety</b>	<ul style="list-style-type: none"> <li>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 schedule<sup>29</sup></li> </ul>	<ul style="list-style-type: none"> <li>Myocarditis after mRNA vaccination<sup>39,41,51</sup> <ul style="list-style-type: none"> <li>Warning in FDA labeling</li> <li>ACIP states vaccine benefit outweighs risk<sup>47</sup></li> <li>Most cases after dose 2</li> <li>Most cases in persons 16-24 years old</li> <li>Most cases in males</li> <li>Median time to onset 2 days after dose 2</li> <li>Most cases were mild; no deaths occurred</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>CDC/FDA reviewed cases of thrombosis-thrombocytopenia syndrome (TTS) and recommend use of the vaccine resume in the US w/o age/gender restriction<sup>18</sup> <ul style="list-style-type: none"> <li>risk highest in women 18-49 years old</li> <li>onset mean of 8 days post-vaccination (range 6-15 days)</li> <li>vaccine labeling now contains information about the risk<sup>4,19</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Injection-site pain, redness and swelling, fatigue, muscle pain, headache, joint pain, nausea, vomiting, fever</li> <li>Increased risk of myocarditis and pericarditis; symptoms began within 10 days of vaccination in most cases</li> </ul>	<ul style="list-style-type: none"> <li>European Medicines Agency (EMA) reports possible link between vaccine and cases of CVST and splanchnic vein thrombosis with thrombocytopenia<sup>20</sup></li> <li>Some countries have suspended or limited use of the vaccine</li> </ul>

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
<b>Some Post-Authorization Reports (continued)</b>					
<b>Safety (continued)</b>	<ul style="list-style-type: none"> <li>■ Myocarditis after mRNA vaccination<sup>39,41,51</sup> <ul style="list-style-type: none"> <li>● FDA warning in labeling</li> <li>● ACIP: benefits outweigh risk of myocarditis<sup>47</sup></li> <li>● Most cases occurred after 2<sup>nd</sup> dose</li> <li>● Most cases in persons 16-24 years old</li> <li>● Most cases in males</li> <li>● Median time to onset 2 days after dose 2</li> <li>● Most cases were mild; no deaths occurred</li> </ul> </li> <li>■ 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</li> <li>■ Cases of herpes zoster reactivation in patients with autoimmune inflammatory reumatic diseases<sup>16</sup></li> <li>■ FDA reviewing adverse events of interest in persons ≥65 years old (pulmonary embolism, acute MI, immune thrombocytopenia, disseminated intravascular coagulation)</li> <li>■ No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]); some confidence intervals were wide<sup>68,69</sup></li> </ul>	<ul style="list-style-type: none"> <li>■ 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</li> <li>■ Delayed cutaneous reactions<sup>17</sup></li> <li>■ 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 people<sup>58-61</sup></li> <li>■ No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]); some confidence intervals were wide<sup>68,69</sup></li> </ul>	<ul style="list-style-type: none"> <li>■ Case of death due to TTS reported in a woman in her late 30's who received the J&amp;J vaccine<sup>83</sup></li> <li>■ Warning added to labeling about increased risk of Guillain-Barré syndrome (GBS) <ul style="list-style-type: none"> <li>■ 100 cases reported after 12.8 million doses</li> <li>■ 95 required hospitalization; 1 death</li> <li>■ Persons &gt;50 years old and men appear to be at greatest risk</li> <li>■ Most cases occurred within 42 days after vaccination</li> </ul> </li> <li>■ CDC and ACOG state that women &lt;50 years old should be aware of the risk of thrombosis with thrombocytopenia syndrome (TTS) associated with the J&amp;J/Janssen vaccine and that FDA-authorized mRNA vaccines are available that have not been associated with this risk<sup>60,61</sup></li> </ul>		<ul style="list-style-type: none"> <li>■ 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 hemorrhage<sup>57</sup></li> <li>■ 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 schedule<sup>29</sup></li> </ul>

	Pfizer/BioNTech	Moderna	J&J (Janssen)	Novavax	AstraZeneca
<b>Some Post-Authorization Reports (continued)</b>					
<b>Safety (continued)</b>	<ul style="list-style-type: none"> <li>■ 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 people<sup>58-61</sup></li> <li>■ 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 reported<sup>76</sup></li> <li>■ Based on reports to v-safe, adverse reactions after 3rd dose were similar to those after 2nd dose<sup>84</sup></li> <li>■ 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</li> </ul>				

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)<sup>70,95</sup>

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

\* CDC recommends a 3<sup>rd</sup> 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>)<sup>63,64</sup>

\*\* 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.<sup>113-114</sup>

**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.
6. News Release. Novavax COVID-19 vaccine demonstrates 89.3% efficacy in UK Phase 3 trial. Available at: <https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3>. Accessed March 19, 2021.
7. J Lopez Bernal et al. Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on covid-19 related symptoms, hospital admissions, and mortality in older adults in England: test negative case-control study. *BMJ* 2021; 373:n1088.
8. M Voysey et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet* 2021; 397:99.
9. V Shinde et al. Efficacy of NVX-CoV2373 Covid-19 vaccine against the B.1.351 variant. *N Engl J Med* 2021; 384:1899.
10. Y Liu et al. Neutralizing activity of BNT162b2-elicited serum. *N Engl J Med* 2021 March 8 (epub).
11. K Wu et al. Serum neutralizing activity elicited by mRNA-1273 vaccine. *N Engl J Med* 2021 March 17 (epub).
12. SA Madhi et al. Efficacy of the ChAdOx1 nCoV-19 Covid-19 vaccine against the B.1.351 variant. *N Engl J Med* 2021; 381:1885.
13. News Release. AZD1222 US Phase III primary analysis confirms safety and efficacy. 2021 March 25. Available at: <https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2021/azd1222-us-phase-iii-primary-analysis-confirms-safety-and-efficacy.html>. Accessed March 26, 2021.
14. RW Frenck et al. Safety, immunogenicity, and efficacy of the BNT162b2 Covid-19 vaccine in adolescents. *N Engl J Med* 2021 May 27 (epub).
15. MG Thompson et al. Interim estimates of vaccine effectiveness of BNT162b2 and mRNA-1273 COVID-19 vaccines in preventing SARS-CoV-2 infection among health care personnel, first responders, and other essential and frontline workers – eight U.S. locations, December 2020-March 2021. *MMWR Morb Mortal Wkly Rep* 2021; 70:495.
16. V Furer et al. Herpes zoster following BNT162b2 mRNA Covid-19 vaccination in patients with autoimmune inflammatory rheumatic disease: a case series. *Rheumatology* 2021 April 12 (epub).
17. KG Blumenthal et al. Delayed large local reactions to mRNA-1273 vaccine against SARS-CoV-2. *N Engl J Med* 2021; 384:1273.



18. FDA. News Release. FDA and CDC lift recommended pause on Johnson & Johnson (Janssen) COVID-19 vaccine use following thorough safety review. 2021 April 23. Available at: <https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough>. Accessed April 26, 2021.
19. Johnson & Johnson COVID-19 vaccine suspended. Med Lett Drugs Ther 2021 April 16 (epub). Available at: <https://secure.medicalletter.org/w5029a>. Accessed April 16, 2021.
20. News Release. European Medicines Agency. AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets. 2021 April 7. Available at: <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>. Accessed April 16, 2021.
21. CDC. COVID-19 breakthrough case investigations and reporting. Available at: <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>. Accessed October 12, 2021.
22. KRW Emary et al. Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomized controlled trial. Lancet 2021; 397:1351.
23. VJ Hall et al. COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study. Lancet 2021 April 23 (epub).
24. N Dagan et al. BNT162b2 mRNA COVID-19 vaccine in a nationwide mass vaccination setting. N Engl J Med 2021; 384:1412.
25. LJ Abu-Raddad and AA Butt. Effectiveness of the BNT162b2 Covid-19 vaccine against the B.1.1.7 and B.1.351 variants. Correspondence. N Engl J Med 2021 May 5 (epub).
26. K Ali et al. Evaluation of mRNA-1273 SARS-CoV-2 vaccine in adolescents. N Engl J Med 2021 August 11 (epub).
27. H Zhou et al. B.1.526 SARS-CoV-2 variants identified in New York City are neutralized by vaccine-elicited and therapeutic monoclonal antibodies. bioRxiv 2021 March 24 (epub). Available at: <https://www.biorxiv.org/content/10.1101/2021.03.24.436620v1>. Accessed May 9, 2021.
28. X Shen et al. Neutralization of SARS-CoV-2 variants B.1.429 and B.1.351. N Engl J Med 2021 April 7 (epub).
29. RH Shaw et al. Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data. Correspondence. Lancet 2021 May 12 (epub).
30. J Lopez Bernal et al. Effectiveness of COVID-19 vaccines against the B.1.617.2 variant. Preprint report. 2021. Available at: <https://khub.net/documents/135939561/430986542/Effectiveness+of+COVID-19+vaccines+against+the+B.1.617.2+variant.pdf/204c11a4-e02e-11f2-d819-b3664107ac42>. Accessed May 26, 2021.
31. A Pegu et al. Durability of mRNA-1273-induced antibodies against SARS-CoV-2 variants. bioRxiv 2021 May 16 (epub). Available at: <https://www.biorxiv.org/content/10.1101/2021.05.13.444010v1>. Accessed May 20, 2021.
32. FS Vahidy et al. Real world effectiveness of COVID-19 mRNA vaccines against hospitalizations and deaths in the United States. medRxiv 2021 April 23 (epub). Available at: <https://www.medrxiv.org/content/10.1101/2021.04.21.21255873v1>. Accessed May 20, 2021.
33. K Wu et al. Preliminary analysis of safety and immunogenicity of a SARS-CoV-2 variant vaccine booster. medRxiv 2021 May 6 (epub). Available at: <https://www.medrxiv.org/content/10.1101/2021.05.05.21256716v1>. Accessed May 20, 2021.
34. EC Wall et al. Neutralising antibody activity against SARS-CoV-2 VOCs B.1.617.2 and B.1.351 by BNT162b2 vaccination. Lancet 2021 June 3 (epub).
35. MW Tenforde et al. Effectiveness of Pfizer-BioNTech and Moderna vaccines against COVID-19 among hospitalized adults aged ≥65 years – United States, January-March 2021. MMWR Morb Mortal Wkly Rep 2021; 70:674.
36. News Release. COVID-19 study shows mRNA vaccines reduce risk of infection by 91% for fully vaccinated people. June 7, 2021. Available at: <https://www.cdc.gov/media/releases/2021/p0607-mrna-reduce-risks.html>. Accessed June 9, 2021.
37. J Stowe et al. Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant. Public Health England 2021 June 14. Available at: [https://khub.net/web/phe-national/public-library/-/document\\_library/v2WsRK3ZIEig/view\\_file/479607329?com\\_liferay\\_document\\_library\\_web\\_portlet\\_DLPortlet\\_INSTANCE\\_v2WsRK3ZIEig\\_redirect=https%3A%2F%2Fkhub.net%3A443%2Fweb%2Fphe-national%2Fpublic-library%2F-%2Fdocument\\_library%2Fv2WsRK3ZIEig%2Fview%2F479607266](https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZIEig/view_file/479607329?com_liferay_document_library_web_portlet_DLPortlet_INSTANCE_v2WsRK3ZIEig_redirect=https%3A%2F%2Fkhub.net%3A443%2Fweb%2Fphe-national%2Fpublic-library%2F-%2Fdocument_library%2Fv2WsRK3ZIEig%2Fview%2F479607266). Accessed June 15, 2021.
38. FDA. Amended Emergency Use Authorization – Concurrence. April 7, 2022. Available at: [https://www.fda.gov/media/157554/download?utm\\_campaign=campaign&utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/media/157554/download?utm_campaign=campaign&utm_medium=email&utm_source=govdelivery). Accessed April 12, 2022.
39. T Shimabukuro. Vaccine Safety Team. CDC COVID-19 Vaccine Task Force. Vaccines and Related Biological Products Advisory Committee (VRBPAC). 2021 June 10. Available at: <https://www.fda.gov/media/150054/download>. Accessed June 15, 2021.
40. LM Dunkle et al. Efficacy and safety of NVX-CoV2373 in adults in the United States and Mexico. N Engl J Med 2022; 386:531.
41. CDC. Selected adverse events reported after COVID-19 vaccination. June 23, 2021. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>. Accessed June 28, 2021.
42. A Sheikh et al. SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness. Lancet 2021; 397:P2461.
43. News Release. Decline in vaccine effectiveness against infection and symptomatic illness. Israel Ministry of Health. 2021 July 5. Available at: <https://www.gov.il/en/departments/news/05072021-03>. Accessed July 15, 2021.
44. S Nasreen et al. Effectiveness of COVID-19 vaccines against variants of concern, Canada. medRxiv 2021 July 3 (epub). Available at: <https://www.medrxiv.org/content/10.1101/2021.06.28.21259420v1>. Accessed July 15, 2021.
45. FDA. Initial results of near real-time safety monitoring of COVID-19 vaccines in persons aged 65 years and older. 2021 July 12. Available at: [https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older?utm_medium=email&utm_source=govdelivery). Accessed July 15, 2021.
46. M Jongeneelen et al. Ad26.COV2.S elicited neutralizing activity against Delta and other SARS-CoV-2 variants of concern. bioRxiv 2021 July 1 (epub). Available at: <https://www.biorxiv.org/content/10.1101/2021.07.01.450707v1>. Accessed July 15, 2021.
47. JW Gargano et al. Use of mRNA COVID-19 vaccine after reports of myocarditis among vaccine recipients: update from the Advisory Committee on Immunization Practices – United States, June 2021. MMWR Morb Mortal Wkly Rep 2021; 70:977.
48. T Tada et al. Comparison of neutralizing antibody titers elicited by mRNA and adenoviral vector vaccine against SARS-CoV-2 variants. bioRxiv 2021 July 19 (epub). Available at: <https://www.biorxiv.org/content/10.1101/2021.07.19.452771v1.full.pdf>. Accessed July 22, 2021.

49. J Lopez Bernal et al. Effectiveness of COVID-19 vaccines against the B.1.617.2 (Delta) variant. N Engl J Med 2021 July 21 (epub).
50. DH Barouch et al. Durable humoral and cellular immune responses 8 months after Ad26.COV2.S vaccination. N Engl J Med 2021 July 14 (epub).
51. FDA News Release. Coronavirus (COVID-19) update: June 25, 2021. Available at: <https://bit.ly/3Bp7TpK>. Accessed July 21, 2021.
52. M Bergwerk et al. COVID-19 breakthrough infections in vaccinated health care workers. N Engl J Med 2021 July 28 (epub).
53. AM Cavanaugh et al. Reduced risk of reinfection with SARS-CoV-2 after COVID-19 vaccination – Kentucky, May-June 2021. MMWR Morb Mortal Wkly Rep. 2021 August 6 (epub).
54. SJ Thomas et al. Six month safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. medRxiv 2021 July 28 (epub). Available at: <https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1>. Accessed August 10, 2021.
55. Moderna. Business updates. Second quarter 2021 financial results. Available at: <https://investors.modernatx.com/static-files/c43de312-8273-4394-9a58-a7fc7d5ed098>. Accessed August 11, 2021.
56. A Puranik et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv. 2021 August 9 (epub). Available at: <https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v2>. Accessed August 11, 2021.
57. S Pavord et al. Clinical features of vaccine-induced immune thrombocytopenia and thrombosis. N Engl J Med 2021 August 11 (epub).
58. American College of Obstetricians and Gynecologists. ACOG and SMFM recommend COVID-19 vaccination for pregnant individuals. Available at: <https://www.acog.org/news/news-releases/2021/07/acog-smfm-recommend-covid-19-vaccination-for-pregnant-individuals>. Accessed August 12, 2021.
59. CDC. New CDC data: COVID-19 vaccination safe for pregnant people. 2021 August 11 Available at: <https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html>. Accessed August 12, 2021.
60. The American College of Obstetricians and Gynecologists. COVID-19 vaccination considerations for obstetric-gynecologic care. 2021 July 30. Available at: <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care>. Accessed August 12, 2021.
61. CDC. New CDC data: COVID-19 vaccination safe for pregnant people. 2021 August 11. Available at: <https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html>. Accessed August 12, 2021.
62. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes additional vaccine dose for certain immunocompromised individuals. 2021 August 12. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>. Accessed August 13, 2021.
63. ND Goswami. ACIP Meeting. Clinical considerations for use of an additional mRNA COVID-19 vaccine dose after a primary mRNA COVID-19 vaccine series for immunocompromised people. 2021 August 13. Available at: <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-13.html>. Accessed August 14, 2021.
64. CDC. COVID-19 vaccines for moderately to severely immunocompromised people. 2021 August 13. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>. Accessed August 14, 2021.
65. FDA. Vaccines and Related Biological Products Advisory Committee September 17, 2021 Meeting Announcement. Available at: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement>. Accessed September 20, 2021.
66. A Fowlkes et al. Among frontline workers before and during B.1.617.2 (Delta) variant predominance – eight U.S. locations, December 2020 – August 2021. MMWR Morb Mortal Wkly Rep 2021 August 24 (epub).
67. YM Bar-On et al. Protection of BNT162b2 vaccine booster against Covid-19 in Israel. N Engl J Med 2021 September 15 (epub).
68. NP Klein et al. Surveillance for adverse events after COVID-19 mRNA vaccination. JAMA 2021 September 3 (epub).
69. KG Blumenthal et al. Safety surveillance of COVID-19 mRNA vaccines through the Vaccine Safety Datalink. Editorial. 2021 September 3 (epub).
70. N Barda et al. Safety of the BNT162b2 mRNA Covid-19 vaccine in a nationwide setting. N Engl J Med 2021; 385:1078.
71. S Oliver. Framework for booster doses of COVID-19 vaccines. CDC. ACIP Meeting August 30, 2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/09-COVID-Oliver-508.pdf>. Accessed September 8, 2021.
72. MW Tenforde et al. Sustained effectiveness of Pfizer-BioNTech and Moderna vaccines against COVID-19 associated hospitalizations among adults – United States, March-July 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1156.
73. M Antonelli et al. Risk factors and disease profile of post-vaccination SARS-CoV-2 infection in UK users of the COVID Symptom Study app: a prospective, community-based, nested, case-control study. Lancet Infect Dis 2021 September 1 (epub).
74. S Nanduri et al. Effectiveness of Pfizer-BioNTech and Moderna vaccines in preventing SARS-CoV-2 infection among nursing home residents before and during widespread circulation of the SARS-CoV-2 B.1.617.2 (Delta) variant. National Healthcare Safety Network, March 1-August 1, 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1163.
75. WH Self et al. Comparative effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) vaccines in preventing COVID-19 hospitalizations among adults without immunocompromising conditions – United States, March-August 2021. MMWR Morb Mortal Wkly Rep 2021 September 17 (epub).
76. J Lee. Vaccines and Related Biological Products Advisory Committee Meeting. FDA review of effectiveness and safety of COMIRNATY (COVID-19 vaccine, mRNA) booster dose. Biologics license application supplement. September 17, 2021. Available at: <https://www.fda.gov/media/152239/download>. Accessed September 20, 2021.
77. News release. Pfizer and BioNTech announce positive topline results from pivotal trial of COVID-19 vaccine in children 5 to 11 years. Available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-positive-topline-results>. Accessed September 20, 2021.
78. FDA News Release. Coronavirus (COVID-19) Update: FDA expands eligibility for COVID-19 vaccine boosters. November 19, 2021. Available at: [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters?utm_medium=email&utm_source=govdelivery). Accessed November 19, 2021.

79. News Release. Johnson & Johnson announces real-world evidence and phase 3 data confirming strong and long-lasting protection of single-shot COVID-19 vaccine in the U.S. September 21, 2021. Available at: <https://www.jnj.com/johnson-johnson-announces-real-world-evidence-and-phase-3-data-confirming-strong-and-long-lasting-protection-of-single-shot-covid-19-vaccine-in-the-us>. Accessed September 23, 2021.
80. JM Polinski et al. Effectiveness of the single-dose Ad26.COV2.S COVID vaccine. medRxiv 2021 September 16. Available at: <https://www.medrxiv.org/content/10.1101/2021.09.10.21263385v2>. Accessed September 23, 2021.
81. CDC. COVID-19 Vaccine Booster Shots. November 19, 2021. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>. Accessed November 20, 2021.
82. SY Tartof et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. Lancet 2021 October 4 (epub).
83. News Release. King County statement on resident who died of rare vaccine-related blood clot. October 5, 2021. Available at: <https://publichealthinsider.com/2021/10/05/king-county-statement-on-resident-who-died-of-rare-vaccine-related-blood-clot/>. Accessed October 7, 2021.
84. AM Hause et al. Safety monitoring of an additional dose of COVID-19 vaccine – United States, August 12-September 19, 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1379.
85. FDA. Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Announcement. Available at: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement>. Accessed October 14, 2021.
86. RL Atmar et al. Heterologous SARS-CoV-2 booster vaccinations – preliminary report. medRxiv 2021 October 13. Available at: <https://www.medrxiv.org/content/10.1101/2021.10.10.21264827v1.full.pdf>. Accessed October 17, 2021.
87. News Release. FDA. Coronavirus (COVID-19) update: FDA takes additional actions on the use of a booster dose for COVID-19 vaccines. Available at: [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines?utm_medium=email&utm_source=govdelivery). Accessed October 20, 2021.
88. News Release. CDC expands eligibility for COVID-19 booster shots. October 21, 2021. Available at: <https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html>. Accessed October 22, 2021.
89. EB Walter et al. Evaluation of the BNT162b2 Covid-19 vaccine in children 5 to 11 years of age. N Engl J Med 2021 November 9 (epub).
90. News Release. Moderna announces positive top line data from phase 2/3 study of COVID-19 vaccine in children 6 to 11 years of age. October 25, 2021. Available at: <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-top-line-data-phase-23-study-covid-19>. Accessed October 28, 2021.
91. News Release. FDA authorizes Pfizer/BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age. October 29, 2021. Available at: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>. Accessed October 29, 2021.
92. CH Bozio et al. Laboratory-confirmed COVID-19 among adults hospitalized with COVID-19-like illness with infection-induced or mRNA vaccine-induced SARS-CoV-2 immunity – nine states, January-September 2021. MMWR Morb Mortal Wkly Rep 2021 October 29 (epub).
93. News Release. CDC recommends pediatric COVID-19 vaccine for children 5 to 11 years. Available at: <https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html>. Accessed November 2, 2021.
94. A Singanayagam et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. 2021 October 29 (epub).
95. N Dagan et al. Adverse effects after BNT162b2 vaccine and SARS-CoV-2 infection, according to age and sex. 2021 October 27 (epub).
96. SM Olson et al. Effectiveness of Pfizer-BioNTech mRNA vaccination against COVID-19 hospitalization among persons aged 12-18 years – United States, June-September 2021. MMWR Morb Mortal Wkly 2021; 70:1483.
97. News Release. CDC expands COVID-19 booster recommendations. November 29, 2021. Available at: <https://www.cdc.gov/media/releases/2021/s1129-booster-recommendations.html>. Accessed November 30, 2021.
98. BA Dickerman et al. Comparative effectiveness of BNT162b2 and mRNA-1273 vaccines in U.S. veterans. N Engl J Med 2021 December 1 (epub).
99. ES Rosenberg et al. Covid-19 vaccine effectiveness in New York State. N Engl J Med 2021 December 1 (epub).
100. MG Thompson et al. Effectiveness of a third dose of mRNA vaccines against COVID-19-associated emergency department and urgent care encounters and hospitalizations among adults during periods of Delta and Omicron variant predominance – VISION Network, 10 states, August 2021-January 2022. MMWR Morb Mortal Wkly Rep 2022 January 21 (epub).
101. FDA News Release. Coronavirus (COVID-19) update: FDA expands eligibility for Pfizer-BioNTech COVID-19 booster dose to 16- and 17-year-olds. December 9, 2021. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-booster-dose-16-and-17>. Accessed December 9, 2021.
102. News Release. CDC expands COVID-19 booster recommendations to 16- and 17-year-olds. December 9, 2021. Available at: <https://www.cdc.gov/media/releases/2021/s1208-16-17-booster.html>. Accessed December 9, 2021.
103. News Release. Pfizer and BioNTech provide update on Omicron variant. December 8, 2021. Available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant>. Accessed December 16, 2021.
104. UK Health Security Agency. SARS-CoV-2 variants of concern and variants under investigation in England. Technical briefing 31. 10 December 2021. Available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1040076/Technical\\_Briefing\\_31.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1040076/Technical_Briefing_31.pdf). Accessed December 16, 2021.
105. W Dejnirattisai et al. Reduced neutralisation of SARS-CoV-2 Omicron-B.1.1.529 variant by post-immunisation serum. medRxiv 2021 December 11 (epub).
106. N Doria-Rose et al. Booster of mRNA-1273 vaccine reduces SARS-CoV-2 Omicron escape from neutralizing antibodies. medRxiv 2021 December 15 (epub).
107. News Release. Pfizer and BioNTech provide update on ongoing studies of COVID-19 vaccine. December 17, 2021. Available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19>. Accessed December 20, 2021.

108. News Release. Moderna announces preliminary booster data and updates strategy to address Omicron variant. December 20, 2021. Available at: <https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Preliminary-Booster-Data-and-Updates-Strategy-to-Address-Omicron-Variant/default.aspx>. Accessed December 21, 2021.
109. FDA News Release. Coronavirus (COVID-19) update: FDA takes multiple actions to expand use of Pfizer-BioNTech COVID-19 vaccine. January 3, 2022. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine>. Accessed January 3, 2022.
110. News Release. CDC strengthens recommendations and expands eligibility for COVID-19 booster shots. May 19, 2022. Available at: <https://www.cdc.gov/media/releases/2022/s0519-covid-booster-acip.html>. Accessed 5/20/2022.
111. FDA News Release. Coronavirus (COVID-19) update: FDA shortens interval for booster dose of Moderna COVID-19 vaccine to five months. Available at: [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-shortens-interval-booster-dose-moderna-covid-19-vaccine-five-months?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-shortens-interval-booster-dose-moderna-covid-19-vaccine-five-months?utm_medium=email&utm_source=govdelivery). Accessed January 7, 2022.
112. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#vaccination-people-immunocompromised>. Accessed February 15, 2022.
113. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. February 22, 2022. Available at: [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F%2Finfo-by-product%2Fclinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F%2Finfo-by-product%2Fclinical-considerations.html). Accessed February 25, 2022.
114. D Moulia. Myocarditis and COVID-19 vaccine intervals: international data and policies. CDC Advisory Committee on Immunization Practices (ACIP). February 4, 2022. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/11-COVID-Moulia-508.pdf>. Accessed February 25, 2022.
115. FDA News Release. Coronavirus (COVID-19) Update: FDA authorizes second booster dose of two COVID-19 vaccines for older and immunocompromised individuals. March 29, 2022. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and>. Accessed March 29, 2022.
116. FDA News Release. Coronavirus (COVID-19) Update: FDA limits use of Janssen COVID-19 vaccine to certain individuals. May 5, 2022. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals>. Accessed May 6, 2022.
117. R Wisch. FDA/CBER. Vaccines and Related Biological Products Advisory Committee meeting. FDA review of effectiveness and safety of Moderna COVID-19 vaccine in children 6 months through 5 years of age. Emergency Use Authorization Amendment. June 15, 2022. Available at: <https://www.fda.gov/media/159254/download>. Accessed June 17, 2022.
118. R Zhang. FDA/CBER. Vaccines and Related Biological Products Advisory Committee meeting. FDA review of effectiveness and safety of Moderna COVID-19 vaccine in children 6 through 17 years of age. Emergency Use Authorization Amendment. June 14, 2022. Available at: <https://www.fda.gov/media/159223/download>. Accessed June 17, 2022.
119. S Wollersheim. FDA/CBER. Vaccines and Related Biological Products Advisory Committee meeting. FDA review of the effectiveness and safety of Pfizer-BioNTech COVID-19 vaccine in children 6 months through 4 years of age. Emergency Use Authorization amendment. June 15, 2022. Available at: <https://www.fda.gov/media/159255/download>. Accessed June 17, 2022.
120. FDA News Release. Coronavirus (COVID-19) Update: FDA authorizes Moderna and Pfizer-BioNTech COVID-19 vaccines for children down to 6 months of age. June 17, 2022. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children>. Accessed June 17, 2022.
121. FDA News Release. Coronavirus (COVID-19) Update: FDA authorizes emergency use of Novavax COVID-19 vaccine, adjuvanted. July 13, 2022. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted>. Accessed July 14, 2022.
122. FDA News Release. FDA roundup: August 19, 2022. Available at: <https://bit.ly/3dKGxmt>. Accessed August 30, 2022.
123. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Novavax COVID-19 vaccine, adjuvanted to prevent coronavirus disease 2019 (COVID-19). August 19, 2022. Available at: <https://bit.ly/3o702aV>. Accessed August 30, 2022.
124. FDA News Release. Coronavirus (COVID-19) Update: FDA authorizes Moderna, Pfizer-BioNTech bivalent COVID-19 vaccines for use as a booster dose. August 31, 2022. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>. Accessed August 31, 2022.

**To support more content like this,  
please consider making a donation\* or becoming a subscriber.**

**The Medical Letter®**  
**Because the source matters.**

The Medical Letter is a nonprofit organization\* that relies solely on subscription fees and donations to support our mission of providing objective, practical, and timely information on drugs and therapeutics.

Our work relies on support from people like you who value credible, unbiased drug information that is free of any commercial interest.

**Subscribe for less than \$3/week.**

\* Medical Letter, Inc. (EIN: 13-1881832) is a nonprofit, tax-exempt organization under Section 501(C)(3) of the Internal Revenue Code. Donations are tax-deductible as allowed by law.

**PRESIDENT:** Mark Abramowicz, M.D.; **VICE PRESIDENT AND EXECUTIVE EDITOR:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School  
**VICE PRESIDENT AND EDITOR IN CHIEF:** Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D. **CONSULTING EDITORS:** Joanna Esterow, PA-C, Mordechai Sacks, DMSc, PA-C, Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

**CONTRIBUTING EDITORS:** Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Ericka L. Crouse, Pharm.D., B.C.P.P., C.G.P., F.A.S.H.P., F.A.S.C.P., Virginia Commonwealth University; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Albert Einstein College of Medicine; David N. Juurlink, BPhm, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; Neal H. Steigbigel, M.D., New York University School of Medicine; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

**MANAGING EDITOR AND DIRECTOR OF CONTENT OPERATIONS:** Susie Wong; **EDITORIAL ASSISTANT:** Karrie Ferrara

**FULFILLMENT AND SYSTEMS MANAGER:** Cristine Romatowski; **EXECUTIVE DIRECTOR OF SALES:** Elaine Reaney-Tomaselli

**EXECUTIVE DIRECTOR OF MARKETING AND COMMUNICATIONS:** Joanne F. Valentino; **INTERIM PUBLISHER:** Jean-Marie Pflomm, Pharm.D.

Founded in 1959 by Arthur Kallet and Harold Aaron, M.D.

**Copyright and Disclaimer:** The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. does not sell advertising or receive any commercial support. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The editors do not warrant that all the material in this publication is accurate and complete in every respect. The editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

#### Subscription Services

**Address:**

The Medical Letter, Inc.  
145 Huguenot St. Ste. 312  
New Rochelle, NY 10801-7537  
www.medicalletter.org

**Customer Service:**

Call: 800-211-2769 or 914-235-0500  
Fax: 914-632-1733  
E-mail: [custserv@medicalletter.org](mailto:custserv@medicalletter.org)

**Permissions:**

To reproduce any portion of this issue,  
please e-mail your request to:  
[permissions@medicalletter.org](mailto:permissions@medicalletter.org)

**Subscriptions (US):**

1 year - \$159; 2 years - \$298;  
3 years - \$398. \$65 per year  
for students, interns, residents,  
and fellows in the US and Canada.  
Reprints - \$45 per issue or article

**Site License Inquiries:**

E-mail: [SubQuote@medicalletter.org](mailto:SubQuote@medicalletter.org)  
Call: 800-211-2769  
Special rates available for bulk  
subscriptions.

Get Connected:  

Copyright 2021. ISSN 0025-732X

The  
Medical  
Letter