## COVID-19 VACCINE COMPARISON CHART from The Medical Letter®

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>FDA Approved for Use in the US</th>
<th>FDA Authorized in US for Emergency Use</th>
<th>Not Authorized in the US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer/BioNTech</td>
<td>Comirnaty (BNT162b2)</td>
<td>Spikevax (mRNA-1273)</td>
<td>J&amp;J (Janssen)</td>
</tr>
<tr>
<td>Vaccine Type</td>
<td>mRNA</td>
<td>mRNA</td>
<td>Adenovirus vector</td>
</tr>
<tr>
<td>Age</td>
<td>≥12 yrs: 30 mcg given as 2 doses 3-8 months apart&lt;sup&gt;13&lt;/sup&gt;-&lt;sup&gt;14&lt;/sup&gt;</td>
<td>≥12 yrs: 100 mcg given as 2 doses 4-8 weeks apart&lt;sup&gt;113&lt;/sup&gt;,&lt;sup&gt;120&lt;/sup&gt;</td>
<td>≥18 years old</td>
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<tr>
<td></td>
<td>6 months-&lt;5 yrs: 30 mcg given as 3 doses at 0, 3, and ≥8 weeks after dose 2&lt;sup&gt;20&lt;/sup&gt;</td>
<td>6 months-&lt;5 yrs: 50 mcg given as 2 doses 4 weeks apart&lt;sup&gt;120&lt;/sup&gt;</td>
<td>Immunocompromised: 3&lt;sup&gt;rd&lt;/sup&gt; dose 28 days after the 2&lt;sup&gt;nd&lt;/sup&gt; dose&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dosage (Primary Series)</td>
<td>Immunocompromised: 3&lt;sup&gt;rd&lt;/sup&gt; dose 28 days after the 2&lt;sup&gt;nd&lt;/sup&gt; dose in ≥5 yrs&lt;sup&gt;62&lt;/sup&gt;-&lt;sup&gt;64&lt;/sup&gt;,&lt;sup&gt;109&lt;/sup&gt;</td>
<td>6-11 yrs: 25 mcg given as 2 doses 4 weeks apart&lt;sup&gt;120&lt;/sup&gt;</td>
<td>Immunocompromised: 3&lt;sup&gt;rd&lt;/sup&gt; dose 28 days after the 2&lt;sup&gt;nd&lt;/sup&gt; dose&lt;sup&gt;6&lt;/sup&gt;-&lt;sup&gt;4&lt;/sup&gt;,&lt;sup&gt;109&lt;/sup&gt;</td>
</tr>
<tr>
<td>Booster (in US)</td>
<td>1 dose (30 mcg for ≥12 yrs; 10 mcg for ≥5 yrs)</td>
<td>1 dose (50 mcg)</td>
<td>1 dose (50 mcg)</td>
</tr>
<tr>
<td></td>
<td>FDA EUA: ≥5 yrs old&lt;sup&gt;78&lt;/sup&gt;,&lt;sup&gt;109&lt;/sup&gt;</td>
<td>FDA EUA: ≥18 years old&lt;sup&gt;7&lt;/sup&gt;</td>
<td>FDA EUA: ≥18 years old&lt;sup&gt;7&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>≥5 months after primary series&lt;sup&gt;109&lt;/sup&gt;</td>
<td>≥5 months after primary series&lt;sup&gt;111&lt;/sup&gt;</td>
<td>≥5 months after primary series&lt;sup&gt;111&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Immunocompromised: ≥3 months after 3&lt;sup&gt;rd&lt;/sup&gt; dose&lt;sup&gt;120&lt;/sup&gt;</td>
<td>Immunocompromised: ≥3 months after 3&lt;sup&gt;rd&lt;/sup&gt; dose&lt;sup&gt;112&lt;/sup&gt;</td>
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</tr>
<tr>
<td></td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; booster ≥4 months after 1&lt;sup&gt;st&lt;/sup&gt; booster of any authorized COVID-19 vaccine in persons ≥50 yrs old or ≥12 yrs old who are immunocompromised (organ transplant or equivalent level of immunocompromise)&lt;sup&gt;115&lt;/sup&gt;</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; booster ≥4 months after 1&lt;sup&gt;st&lt;/sup&gt; booster of any authorized COVID-19 vaccine in persons ≥50 yrs old or immunocompromised (organ transplant or equivalent level of immunocompromise)</td>
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</tr>
<tr>
<td></td>
<td>CDC: ≥5 yrs old should receive a booster&lt;sup&gt;37&lt;/sup&gt;,&lt;sup&gt;110&lt;/sup&gt;</td>
<td>FDA and CDC authorized heterologous (&quot;mix and match&quot;) boosters for persons ≥18 years old&lt;sup&gt;97&lt;/sup&gt;</td>
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</tr>
<tr>
<td>Variants</td>
<td>Pfizer/BioNTech</td>
<td>Moderna</td>
<td>J&amp;J (Janssen)</td>
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<tr>
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</tr>
<tr>
<td>Overall</td>
<td>95% (7 days after 2nd dose); 91% (6 mos)</td>
<td>94.1% (14 days after 2nd dose); 93.2% (~5.3 mos)</td>
<td>66.1% (overall)</td>
</tr>
<tr>
<td>In Elderly Persons</td>
<td>94.7% (≥65 yrs); &gt;80% vs hosp. (≥75 yrs); 71%; 74.7%</td>
<td>86.4% (≥65 yrs); &gt;80% vs hosp. (≥75 yrs); 71%; 74.7%</td>
<td>66.2% (≥60 yrs)</td>
</tr>
<tr>
<td>In Adolescents (12-15 years old)</td>
<td>100%</td>
<td>100%; 96%</td>
<td>-</td>
</tr>
<tr>
<td>In Children (5-11/6-11 years old)</td>
<td>90.7% (10 mcg); nAb similar to 16-25 yr olds</td>
<td>Antibody response similar to 18-25 yr olds</td>
<td>-</td>
</tr>
<tr>
<td>In Children (2-&lt;5/5 years old)</td>
<td>Antibody response did not meet non-inferiority for 2 doses; antibody response similar to 16-25 yr olds for 3 doses</td>
<td>Antibody response similar to 18-25 yr olds</td>
<td>-</td>
</tr>
<tr>
<td>In Children (6-23 months old)</td>
<td>Antibody response similar to older subgroups</td>
<td>Antibody response similar to 18-25 yr olds</td>
<td>-</td>
</tr>
<tr>
<td>In Severe Disease</td>
<td>90%; 97.5%; 84-86%; 88% (vs hosp)</td>
<td>100%; 98.2%; 84-86%; 93% (vs hosp)</td>
<td>85.4%; US: 87.6%; 71%, 81% (vs hosp)</td>
</tr>
<tr>
<td>COVID-19 Death</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Delta (India; B.1.617.2)</td>
<td>87.9%; 79%; 64.4; 96% vs hosp.; 87.4%; 88% (30.7 1 dose); 46%; 39-84%; 75-95% vs hosp.; 53.1%; 72.3%</td>
<td>72% (1 dose); 76%; 39-84%; 75-95% vs hosp.; 53.1%; 77.8%</td>
<td>78%; 69.4%; 1.6-fold lower nAb; 5.4-fold lower nAb</td>
</tr>
<tr>
<td>Alpha (B.1.1.7; UK)</td>
<td>85%; 89.5%; 89%; 93.7% (48.7% 1 dose); 91.3%</td>
<td>92%; 96.9%; in vitro activity</td>
<td>~60-75%; 86.6%</td>
</tr>
<tr>
<td>Beta (B.1.351; South Africa)</td>
<td>75.0%; 84%; 100%</td>
<td>77% (1 dose); in vitro lower activity</td>
<td>64.0%; 6.7-fold lower nAb</td>
</tr>
<tr>
<td>Gamma (P.1; Brazil)</td>
<td>84%; in vitro activity</td>
<td>77% (1 dose); in vitro lower activity</td>
<td>68.1%</td>
</tr>
<tr>
<td>Iota (NY; B.1.526)</td>
<td>In vitro lower activity</td>
<td>In vitro lower activity</td>
<td>Data not available</td>
</tr>
<tr>
<td>Epsilon (B.1.427/ B.1.429; CA)</td>
<td>In vitro lower activity</td>
<td>In vitro lower activity</td>
<td>Data not available</td>
</tr>
<tr>
<td>Omicron (B.1.529)</td>
<td>30%-40% (2 doses); 70%-80% (3 doses); 70% vs hosp; 90% vs hosp (3 doses)</td>
<td>90% vs hosp (3 doses); lower nAb, increased with booster</td>
<td>Data not available</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Transport and Storage</th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>J&amp;J (Janssen)</th>
<th>AstraZeneca</th>
<th>Novavax</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purple cap vials (≥12 yrs; must dilute):</strong></td>
<td>▪ -60 to -90°C</td>
<td>▪ -50 to -15°C</td>
<td>▪ 2-8°C x 11 months</td>
<td>▪ 2-8°C</td>
<td>▪ 2-8°C</td>
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<tr>
<td>▪ Alt: -25 to -15°C x 2 wks</td>
<td>▪ Alt: 2-8°C x 12 hrs</td>
<td></td>
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</tr>
<tr>
<td><strong>Gray cap vials (≥12 yrs; do not dilute):</strong></td>
<td>▪ -60 to -90°C (transport)</td>
<td>▪ Light blue border vials (≥12 yrs)</td>
<td>▪ Magenta border vials (6 months-5 yrs)</td>
<td></td>
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</tr>
<tr>
<td><strong>Orange cap vials (5-11 yrs; must dilute):</strong></td>
<td>▪ -60 to -90°C or -25 to -15°C (for transport only)</td>
<td>▪ Teal &amp; purple border vials (6-11 yrs)</td>
<td></td>
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<tr>
<td><strong>Maroon cap vials (6 months-&lt;5 yrs; must dilute):</strong></td>
<td>▪ -60 to -90°C or -25 to -15°C (for transport only)</td>
<td>▪ Black border vials (≥12 yrs)</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Excursions at distribution</th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>J&amp;J (Janssen)</th>
<th>AstraZeneca</th>
<th>Novavax</th>
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<tr>
<td><strong>Purple cap vials (≥12 yrs):</strong></td>
<td>▪ 2-8°C x 1 month</td>
<td>▪ 2-8°C x 30 days</td>
<td>▪ 9-25°C x 12 hrs</td>
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<tr>
<td>▪ 8-25°C x ≤2 hrs</td>
<td>▪ 8-25°C x 24 hrs</td>
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<tr>
<td>▪ Gray cap vials (≥12 yrs; do not dilute):</td>
<td>▪ 2-8°C x 10 weeks</td>
<td>▪ Black border vials (≥12 yrs)</td>
<td>▪ Magenta border vials (6 months-5 yrs)</td>
<td></td>
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<tr>
<td>▪ 8-25°C x 12 hrs</td>
<td>▪ Light blue border vials (≥12 yrs)</td>
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<tr>
<td>▪ Orange cap vials (5-11 yrs):</td>
<td>▪ 2-8°C x 10 weeks</td>
<td>▪ Teal &amp; purple border vials (6-11 yrs)</td>
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<td>▪ 8-25°C x 12 hrs</td>
<td>▪ Magenta border vials (6 months-5 yrs)</td>
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<td>▪ Black border vials (≥12 yrs)</td>
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<td>▪ 8-25°C x 12 hrs</td>
<td>▪ Light blue border vials (≥12 yrs)</td>
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<table>
<thead>
<tr>
<th>After Puncture/Dilution</th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>J&amp;J (Janssen)</th>
<th>AstraZeneca</th>
<th>Novavax</th>
</tr>
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<tbody>
<tr>
<td><strong>Purple cap vials (≥12 yrs; must dilute):</strong></td>
<td>▪ 2-25°C x 12 hrs</td>
<td>▪ 2-8°C x 6 hrs</td>
<td>▪ 2-8°C x 12 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ 2-25°C x 6 hrs</td>
<td>▪ 8-25°C x 2 hrs</td>
<td></td>
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<td>▪ 2-25°C x 12 hrs</td>
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<tr>
<td><strong>Maroon cap vials (6 months-&lt;5 yrs; must dilute):</strong></td>
<td>▪ 2-25°C x 12 hrs</td>
<td>▪ Magenta border vials (6 months-5 yrs)</td>
<td></td>
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</tbody>
</table>

| ▪ 2-25°C x 6 hrs | ▪ 9-30°C x 6 hrs | | | | |

| ▪ 2-25°C x 12 hrs | | | | | |
| ▪ 8-25°C x 2 hrs | | | | | |

After Puncture/Dilution: Purple cap vials (≥12 yrs; must dilute): ▪ 2-25°C x 12 hrs
Black border vials (≥12 yrs)
Light blue border vials (≥12 yrs)
Teal & purple border vials (6-11 yrs)
Magenta border vials (6 months-5 yrs)

AstraZeneca

Panelists: Pfizer/BioNTech
Moderna
J&J (Janssen)
AstraZeneca
Novavax

Storage Requirements

Transport and Storage: Purple cap vials (≥12 yrs; must dilute):
- -60 to -90°C
- Alt: -25 to -15°C x 2 wks

Gray cap vials (≥12 yrs; do not dilute):
- -60 to -90°C (transport)

Orange cap vials (5-11 yrs; must dilute):
- -60 to -90°C or -25 to -15°C (for transport only)

Maroon cap vials (6 months-<5 yrs; must dilute):
- -60 to -90°C or -25 to -15°C (for transport only)

Excursions at distribution: Purple cap vials (≥12 yrs):
- 2-8°C x 1 month
- 8-25°C x ≤2 hrs

Gray cap vials (≥12 yrs; do not dilute):
- 2-8°C x 10 weeks
- 8-25°C x 12 hrs

Orange cap vials (5-11 yrs):
- 2-8°C x 10 weeks
- 8-25°C x 12 hrs

Maroon cap vials (6 months-<5 yrs; must dilute):
- 2-8°C x 10 weeks
- 8-25°C x 12 hrs

Evaluation of storage requirements for different vaccine types and storage conditions.
### Efficacy

**Pooled Data with Both mRNA Vaccines:**
- 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\(^\text{15,36}\)
- 96% (hospitalization) and 98.7% (death)\(^\text{30}\)
- 94% (hospitalization) in ≥65 years old fully vaccinated (64% in partially vaccinated)\(^\text{35}\)
- 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)\(^\text{33}\)
- 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\(^\text{73}\)
- Efficacy vs hospitalization: 86% 2-12 weeks after 2nd dose; 84% 13-24 weeks after 2nd dose (MMWR)\(^\text{71}\)
- 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 infection\(^\text{36}\)
- In U.S. veterans, risk of COVID-19 outcomes was lower after mRNA vaccination; risks were lower with Moderna vaccine than with Pfizer/BioNTech vaccine\(^\text{98}\)

**Data with Pfizer/BioNTech Vaccine:**
- 46% after 1st dose and 92% after 2nd dose (Israel)\(^\text{94}\)
- Single dose ~80% effective against hospital admission in persons >70 years old\(^\text{7}\)
- Study of breakthrough infections in Israel reported 39 infections/1497 fully vaccinated health care workers; most mild or asymptomatic; symptoms >6 weeks in 19%\(^\text{62}\)
- **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)\(^\text{97}\)
- 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 months\(^\text{82}\)5-11 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 persons\(^\text{94}\)

**AstraZeneca**
- Single dose ~73% effective against symptomatic COVID-19 and ~ 80% effective against hospital admission in persons >70 years old\(^\text{7}\)
- 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

**Novavax**
- 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\(^\text{94}\)

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**Data with Moderna Vaccine:**
- 93% up to 6 months\(^\text{91}\) effectiveness 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 months\(^\text{82}\)5-11 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
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**J&J (Janssen)**
- 90.7% in descriptive analysis (16 cases placebo vs 3 case vaccine)
### Efficacy (continued)

**Data with Janssen/J&J Vaccine:**
- 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 dose.\(^{37}\)
- Real-world, cohort study reported estimated vaccine efficacy 79% vs COVID-19 infection, 81% vs hospitalization, 78% vs Delta, and 64% in immunocompromised.\(^{50}\)

**Pooled Data All Available Vaccines:**
- 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.\(^{66}\)
- Vaccine Mixing: phase 1/2 trial in 458 persons vaccinated with a different booster than primary series {J&J, Moderna, Pfizer/BioNTech}.\(^{86}\)
  - 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 neutralizing levels at baseline (before booster) were lower for Pfizer/BioNTech (3-fold) and J&J (10-fold) recipients than for Moderna recipients

**CDC report (all vaccines available in the US)**\(^{21}\) October 4th Report
(CDC now monitoring only hospitalized or fatal cases instead of all cases)
- 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 asymptomatic or not COVID-related

### Safety

**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.\(^{29}\)

**Myocarditis after mRNA vaccination**\(^{39,41,51}\)
- Warning in FDA labeling
- ACIP states vaccine benefit outweighs risk.\(^{47}\)
- 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

**CDC/FDA reviewed cases of thrombosis-thrombocytopenia syndrome (TTS) and recommend use of the vaccine resume in the US w/o age/gender restriction**\(^{18}\)
- 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.\(^{5,19}\)

**European Medicines Agency (EMA) reports possible link between vaccine and cases of CVST and splanchnic vein thrombosis with thrombocytopenia**\(^{20}\)

**Some countries have suspended or limited use of the vaccine**
### Safety (continued)

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<thead>
<tr>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>J&amp;J (Janssen)</th>
<th>AstraZeneca</th>
<th>Novavax</th>
</tr>
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</table>
| **Myocarditis after mRNA vaccination**[39,41,51]  
  - FDA warning in labeling  
  - ACIP: benefits outweigh risk of myocarditis[47]  
  - 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  
  - Delayed cutaneous reactions[17]  
  - 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[58,61]  
  - No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]): some confidence intervals were wide[58,69] | **Case of death due to TTS reported in a woman in her late 30’s who received the J&J vaccine[63]**  
  - Warning added to labeling about increased risk of Guillain-Barré syndrome (GBS)  
  - 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[60,62]  
  - 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[57] | **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**[23] | **No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]): some confidence intervals were wide**[58,69] | **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**  
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  - No significant association with vaccination and 23 serious outcomes in interim analysis of surveillance data (Vaccine Safety Datalink [VSD]): some confidence intervals were wide[58,69] |
### Safety (continued)

- 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.

- 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.

- Based on reports to v-safe, adverse reactions after 3rd dose were similar to those after 2nd dose.

- 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)\textsuperscript{70,95} | | |

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

* CDC recommends a 3\textsuperscript{rd} 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 immunosuppressants, 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\textsuperscript{10,14}

** 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.\textsuperscript{113-114}

**For more information see** [Treatments Considered for COVID-19](https://www.fda.gov/media/146304/download)

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