COVID-19 vaccines in Children

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ACIP Meeting
October 19, 2022
COVID-19-associated hospitalizations among children and adolescents ages 6 months – 17 years, COVID-NET

March 21, 2020 – October 1, 2022

Timeline of recommendations for pediatric COVID-19 vaccines

**Primary series**
- **Ages ≥16 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages ≥18 years** Moderna COVID-19 vaccine
- **Ages 12–15 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 5–11 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 12–15 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 5–11 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 5–11 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 6 months–4 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 6 months–5 years** Moderna COVID-19 vaccine
- **Ages 6–17 years** Moderna COVID-19 vaccine
- **Ages ≥12 years** Novavax COVID-19 vaccine

**Booster doses**
- **Ages ≥16 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 12–15 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 5–11 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 12–15 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages 5–11 years** Pfizer-BioNTech COVID-19 vaccine
- **Ages ≥12 years** Pfizer-BioNTech Bivalent COVID-19 vaccine
- **Ages ≥18 years** Moderna Bivalent COVID-19 vaccine
- **Ages 6–17 years** Moderna Bivalent COVID-19 vaccine
- **Ages 5–11 years** Pfizer-BioNTech Bivalent COVID-19 vaccine
- **Ages 6–17 years** Moderna Bivalent COVID-19 vaccine
- **Ages ≥12 years** Novavax COVID-19 vaccine
Data to inform pediatric booster recommendations
Monovalent Pfizer-BioNTech COVID-19 vaccine

Booster dose recommendations for children and adolescents discussed at previous ACIP meetings:

- Recommendations for adolescents *ages 12–15 years* based on safety data from Israel, waning antibody titers and vaccine effectiveness after a primary series in the setting of Omicron, and during peak of winter Omicron surge

- Recommendations for children *ages 5–11 years* based on clinical trial as well as post-authorization safety data

  • Booster dose achieved antibody levels higher than after primary series
  • Reactogenicity after a booster dose similar to what was seen after a primary series
  • Rates of myocarditis after primary series in children ages 5–11 years considerably lower than rates in adolescents

Data to inform pediatric booster recommendations
Monovalent Moderna COVID-19 vaccine

- Booster dose studied in ~2600 children and adolescents:
  - 50mcg booster studied in 1349 adolescents 12–17 years
  - 25mcg booster dose studied in 1294 children ages 5–11 years
- 1 Serious Adverse Event (SAE) unrelated to vaccine in a child 5–11 years; no SAEs in adolescents 12–17 years
- Reactogenicity symptoms similar to what was seen for booster doses in other age groups
- Antibody levels after the booster dose were 4–5 times higher than what was seen after the primary series
Data to inform booster recommendations

Bivalent mRNA COVID-19 vaccines

- At the September 1, 2022 meeting, ACIP discussed bivalent mRNA COVID-19 vaccines for all individuals ages ≥5 years who were previously recommended to receive a monovalent booster dose¹

- >600 million mRNA doses administered
- Clinical data from >1,700 people
- Antibody studies and antigenic cartography
- Modeling data

Myocarditis and COVID-19 vaccines

- Risk of myocarditis/pericarditis has been identified after COVID-19 vaccines
  - Risk is rare and primarily observed in adolescent and young adult males, within the first week after receiving the second dose or booster dose of an mRNA COVID-19 vaccine

- Most individuals with myocarditis/pericarditis have fully recovered at follow-up\(^1\)

- The risk of adverse cardiac outcomes were 1.8 – 5.6 times higher after SARS-CoV-2 infection than after mRNA COVID-19 vaccination among males ages 12 – 17 years\(^2\)

- Interval of 8 weeks between vaccine doses may further lower myocarditis risk

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2. https://www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm?s_cid=mm7114e1_w
Benefit-risk assessment of COVID-19 vaccines

- ACIP has reviewed the balance of benefits and risks **regularly**
  - Primary series for adolescents and young adults: June 23, 2021
  - Primary series for individuals 16-29 years: August 30, 2021
  - Booster doses for individuals ≥18 years: September 23, 2021
  - Booster doses for adolescents 12-15 years: January 5, 2022
  - Booster doses for children 5-11 years: May 19, 2022
  - Bivalent booster doses for individuals ≥5 years: September 1, 2022

- Each time ACIP has evaluated the benefits and risks of mRNA COVID-19 vaccines, ACIP has determined that the **benefits outweigh the risks**
Post-authorization monitoring for COVID-19 vaccines

- Since authorization, **22** ACIP meetings focused on COVID-19 vaccines
  - COVID-19 vaccine effectiveness (VE) data presented at **11** ACIP meetings
  - COVID-19 vaccine safety data presented at **21** ACIP meetings

- CDC evaluates VE through multiple observational studies employing various methods and using information collected through different surveillance platforms, electronic health records, or prospective studies

- COVID-19 vaccines continue to undergo the most comprehensive and intense safety monitoring in U.S. history
VISION: Pfizer-BioNTech VE for ED/UC visits by number of doses and time since last dose receipt for children and adolescents during Omicron, mid-Dec 2021–mid-Jul 2022

<table>
<thead>
<tr>
<th>Vaccination status (days since most recent dose)</th>
<th>Total</th>
<th>SARS-CoV-2 positive, N</th>
<th>Adjusted VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>21,009</td>
<td>1,375</td>
<td>Ref</td>
</tr>
<tr>
<td>2 doses (14-59)</td>
<td>1,151</td>
<td>72</td>
<td>51 (34-64)</td>
</tr>
<tr>
<td>2 doses (60-149)</td>
<td>4,068</td>
<td>179</td>
<td>22 (6-36)</td>
</tr>
<tr>
<td>2 doses (≥150)</td>
<td>1,338</td>
<td>109</td>
<td>18 (-4-35)</td>
</tr>
<tr>
<td>3 doses (≥7)</td>
<td>973</td>
<td>43</td>
<td>63 (48-73)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12-15 years</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>7,318</td>
<td>1,443</td>
<td>Ref</td>
</tr>
<tr>
<td>2 doses (14-59)</td>
<td>219</td>
<td>27</td>
<td>60 (37-74)</td>
</tr>
<tr>
<td>2 doses (60-149)</td>
<td>1,082</td>
<td>196</td>
<td>42 (30-53)</td>
</tr>
<tr>
<td>2 doses (≥150)</td>
<td>3,308</td>
<td>587</td>
<td>14 (2-24)</td>
</tr>
<tr>
<td>3 doses (≥7)</td>
<td>973</td>
<td>43</td>
<td>63 (48-73)</td>
</tr>
</tbody>
</table>

Previously presented to ACIP Sept 1, 2022

CDC, preliminary unpublished data. Individuals with prior infections excluded. ED/UC = Emergency Department/Urgent Care
Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying medical conditions, and propensity to be vaccinated
COVID-like illness: included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms (cough, fever, dyspnea, vomiting, or diarrhea)
mRNA COVID-19 vaccine safety of primary series vaccination in children ages 6 months–5 years

Previously presented to ACIP Sept 1, 2022

- Initial safety findings of both mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are consistent with those observed in the clinical trials
- Systemic and local reactions are commonly reported adverse events
- Vaccination errors are also being reported to VAERS
- No unexpected safety findings to date
- No evidence of an increased risk for myocarditis following mRNA COVID-19 vaccination in children ages 6 months–5 years

VAERS reporting rates of verified myocarditis per 1 million mRNA COVID-19 vaccinations (Pfizer-BioNTech and Moderna combined), days 0–7 post-vaccination*;†
Previously presented to ACIP Sept 1, 2022

<table>
<thead>
<tr>
<th>Age group</th>
<th>Male</th>
<th>Female</th>
<th>Male</th>
<th>Female</th>
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</thead>
<tbody>
<tr>
<td>5–11 years</td>
<td>2.5</td>
<td>0.7</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>12–15 years</td>
<td>47.1</td>
<td>4.2</td>
<td>12.9</td>
<td>0.7</td>
</tr>
<tr>
<td>16–17 years</td>
<td>78.7</td>
<td>7.4</td>
<td>21.6</td>
<td>0.0</td>
</tr>
<tr>
<td>18–24 years</td>
<td>39.3</td>
<td>3.9</td>
<td>13.1</td>
<td>0.6</td>
</tr>
<tr>
<td>25–29 years</td>
<td>15.3</td>
<td>3.5</td>
<td>4.4</td>
<td>2.2</td>
</tr>
<tr>
<td>30–39 years</td>
<td>7.8</td>
<td>1.0</td>
<td>1.9</td>
<td>0.9</td>
</tr>
<tr>
<td>40–49 years</td>
<td>3.3</td>
<td>1.6</td>
<td>0.2</td>
<td>0.6</td>
</tr>
<tr>
<td>50–64 years</td>
<td>0.7</td>
<td>0.5</td>
<td>0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>65+ years</td>
<td>0.3</td>
<td>0.5</td>
<td>0.7</td>
<td>0.2</td>
</tr>
</tbody>
</table>

* As of August 18, 2022. Reports verified to meet case definition by provider interview or medical record review.
† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 risk interval, this estimated background is **0.2 to 2.2 per 1 million person-day 0–7 risk interval** (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period).

VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Pfizer-BioNTech vaccination in people ages 5–39 years, dose 2 and 1st booster*

Previously presented to ACIP Sept 1, 2022

*Primary series surveillance for people ages ≥18 years ended May 21, 2022 All other data through August 20, 2022.


<table>
<thead>
<tr>
<th>Age Group</th>
<th>Gender</th>
<th>Cases</th>
<th>Dose 2 admin</th>
<th>Incidence rate/ million doses (95% CI)</th>
<th>1st boosters admin</th>
<th>Incidence rate/ million doses (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-11 years</td>
<td>Males</td>
<td>3</td>
<td>207,958</td>
<td>14.4 (3.0 – 42.2)</td>
<td>0</td>
<td>50,415</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>0</td>
<td>202,596</td>
<td>0.0 (0.0 – 14.8)</td>
<td>0</td>
<td>49,261</td>
</tr>
<tr>
<td>12–15 years</td>
<td>Males</td>
<td>31</td>
<td>205,955</td>
<td>150.5 (102.3 – 213.6)</td>
<td>5</td>
<td>81,613</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>5</td>
<td>204,074</td>
<td>24.5 (8.0 – 57.2)</td>
<td>0</td>
<td>84,114</td>
</tr>
<tr>
<td>16–17 years</td>
<td>Males</td>
<td>14</td>
<td>102,091</td>
<td>137.1 (75.0 – 230.1)</td>
<td>9</td>
<td>47,874</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>1</td>
<td>107,173</td>
<td>9.3 (0.2 – 52.0)</td>
<td>2</td>
<td>55,004</td>
</tr>
<tr>
<td>18–29 years</td>
<td>Males</td>
<td>27</td>
<td>331,889</td>
<td>81.4 (53.6 – 118.4)</td>
<td>7</td>
<td>166,973</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>2</td>
<td>400,321</td>
<td>5.0 (0.6 – 18.0)</td>
<td>1</td>
<td>240,226</td>
</tr>
<tr>
<td>30–39 years</td>
<td>Males</td>
<td>5</td>
<td>341,527</td>
<td>14.6 (4.8 – 34.2)</td>
<td>3</td>
<td>197,554</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>3</td>
<td>410,713</td>
<td>7.3 (1.5 – 21.3)</td>
<td>1</td>
<td>268,412</td>
</tr>
</tbody>
</table>
COVID-19 vaccine uptake among children and adolescents
Through October 12, 2022

**Children 6 months–4 years of age**
1.4 million first doses administered
6.9% of children in this age group

**Children 5–11 years of age**
11.1 million first doses administered
38.6% of children in this age group
1.4 million booster doses administered
15.6% of children in this age group with a primary series

**Adolescents 12–17 years of age**
18.0 million first doses administered
71.1% of adolescents
4.5 million booster doses administered
29.3% of adolescents with a primary series

COVID-19 vaccine uptake among children and adolescents

December 2020 – October 2022

COVID-19 vaccine recommendations

- People **ages 6 months and older** are recommended to receive a **primary series** of any age-appropriate FDA-approved or FDA-authorized monovalent COVID-19 vaccine.

- People **ages 5 years and older** are recommended to receive **1 bivalent mRNA booster dose** after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s).

- **Monovalent** mRNA vaccines are **no longer authorized** as booster doses.
Booster Recommendations: Bivalent Booster, Continued

- **Homologous** (the same) and **heterologous** (“mix and match”) boosters are allowed*; no preference

*Only Pfizer-BioNTech bivalent booster is authorized for people age 5 years. Both Pfizer-BioNTech and Moderna bivalent boosters are authorized for people ages 6 years and older.
COVID-19 Vaccination Schedule for Children and Adolescents Who Are NOT Moderately or Severely Immunocompromised
Pediatric Schedule: Ages 6 months–4 Years

**Ages 6 months–4 years**
(Primary Series: Moderna)

- 4-8 weeks

**Ages 6 months–4 years**
(Primary Series: Pfizer-BioNTech)

- 3-8 weeks
- At least 8 weeks
Pediatric Schedule: Ages 5–11 Years

Ages 5 years
(Primary Series: Moderna or Pfizer-BioNTech)

- Primary
- 3-8 or 4-8 weeks*
- Primary
- At least 2 months
- ONLY Pfizer Bivalent Booster
- Regardless of previous monovalent booster doses given

Ages 6–11 years
(Primary Series: Moderna or Pfizer-BioNTech)

- Primary
- 3-8 or 4-8 weeks*
- Primary
- At least 2 months
- Pfizer or Moderna Bivalent Booster
- Regardless of previous monovalent booster doses given

*3-8 week interval for Pfizer-BioNTech; 4-8 week interval for Moderna
Pediatric Schedule: Ages 12-17 Years

Ages 12–17 years
(Primary Series: Moderna, Novavax, or Pfizer-BioNTech)

Primary

3-8 or 4-8 weeks*

Primary

At least 2 months

Pfizer or Moderna Bivalent Booster

Regardless of previous monovalent booster doses given

*3-8 week interval for Pfizer-BioNTech; 4-8 week interval for Moderna
COVID-19 Vaccination Schedule for Children and Adolescents Who ARE Moderately or Severely Immunocompromised
Ages 6 months–4 years (Primary Series: Moderna)

Ages 6 months–4 years (Primary Series: Pfizer-BioNTech)
Ages 5 years
(Primary Series: Moderna or Pfizer-BioNTech)

Primary → 3 or 4 weeks* → Primary → At least 4 weeks → Primary → At least 2 months

Regardless of previous monovalent booster doses given

Ages 6–11 years
(Primary Series: Moderna or Pfizer-BioNTech)

Primary → 3 or 4 weeks* → Primary → At least 4 weeks → Primary → At least 2 months

Regardless of previous monovalent booster doses given

*3-week interval for Pfizer-BioNTech; 4-week interval for Moderna
Pediatric Schedule: Ages 12–17 Years (Moderately or Severely Immunocompromised)

**Ages 12–17 years**
(Primary Series: Moderna or Pfizer-BioNTech)

- Primary
- 3 or 4 weeks*
- Primary
- At least 4 weeks
- Primary
- At least 2 months

Regardless of previous monovalent booster doses given

**Ages 12–17 years**
(Primary Series: Novavax)

- Primary
- 3 weeks
- Primary
- At least 2 months

Regardless of previous monovalent booster doses given

*3-8 week interval for Novavax or Pfizer-BioNTech; 4-8 week interval for Moderna
# Complexity of pediatric mRNA COVID-19 vaccines

<table>
<thead>
<tr>
<th>Pfizer-BioNTech COVID-19 vaccines</th>
<th>Ages 6 months–4 years</th>
<th>Ages 5–11 years (monovalent)</th>
<th>Ages 5–11 years (bivalent)</th>
<th>Ages ≥12 years (monovalent)</th>
<th>Ages ≥12 years (bivalent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized dose type</td>
<td>Primary</td>
<td>Primary</td>
<td>Booster</td>
<td>Primary</td>
<td>Booster</td>
</tr>
<tr>
<td>Vial cap color</td>
<td>Maroon</td>
<td>Orange</td>
<td>Orange</td>
<td>Gray</td>
<td>Gray</td>
</tr>
<tr>
<td>Composition</td>
<td>Monovalent</td>
<td>Monovalent</td>
<td>Bivalent</td>
<td>Monovalent</td>
<td>Bivalent</td>
</tr>
<tr>
<td>Dose</td>
<td>3 mcg</td>
<td>10 mcg</td>
<td>10 mcg</td>
<td>30 mcg</td>
<td>30 mcg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderna COVID-19 vaccines</th>
<th>Ages 6 months–5 years</th>
<th>Ages 6–11 years</th>
<th>Ages ≥6 years</th>
<th>Ages ≥12 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized dose type</td>
<td>Primary</td>
<td>Primary</td>
<td>Booster</td>
<td>Primary</td>
</tr>
<tr>
<td>Vial cap color</td>
<td>Dark blue</td>
<td>Dark blue</td>
<td>Dark Blue</td>
<td>Red</td>
</tr>
<tr>
<td>Label border color</td>
<td>Magenta</td>
<td>Purple</td>
<td>Gray</td>
<td>Light blue</td>
</tr>
<tr>
<td>Composition</td>
<td>Monovalent</td>
<td>Monovalent</td>
<td>Bivalent</td>
<td>Monovalent</td>
</tr>
<tr>
<td>Dose</td>
<td>25 mcg</td>
<td>50 mcg</td>
<td>6–11 years: 25 mcg ≥12 years: 50 mcg</td>
<td>100 mcg</td>
</tr>
</tbody>
</table>
Pediatric COVID-19 vaccines

- COVID-19 vaccination is the single **best way** to protect people from serious COVID-19 illness
  - COVID-19 vaccines continue to be effective in reducing the risk of severe disease, hospitalization and death, including against the currently circulating Omicron variants
  - Many children haven’t yet initiated COVID-19 vaccine primary series

- The **benefits** of COVID-19 vaccination **outweigh** the known and potential risks, including the very small risk of myocarditis or pericarditis
Pediatric COVID-19 vaccines

- Over **30 million children and adolescents** have received at least one COVID-19 vaccine dose

- Incorporation of COVID-19 vaccines in the immunization schedule and the Vaccines for Children (VFC) program is an important step toward inclusion of COVID-19 vaccines in routine vaccination program

- Details of implementation for the COVID-19 vaccine VFC program will require ongoing work, but ACIP vote allows the process to **begin**

- **Equitable** access to COVID-19 vaccines for **all ages and populations** remains critically important
Acknowledgements

- Coronavirus and Other Respiratory Viruses Division (proposed)
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  - Sierra Scarbrough
For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348  www.cdc.gov

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