89th in a series of calls, initiated in 2020 by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19.

The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

This webinar is being recorded and can be found online at [www.idsgociety.org/cliniciancalls](http://www.idsgociety.org/cliniciancalls).
COVID-19 Summer Update: Where We are Now, Where We are Going

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
COVID-19 Response Clinical Team, Late Sequelae Unit
U.S. Centers for Disease Control and Prevention

COVID-19 Vaccination in Children Under 5 Years

Highlights from the June 16-17 VRBPAC Meeting
Archana Chatterjee, MD, PhD
Dean, Chicago Medical School and Vice President for Medical Affairs, Rosalind Franklin University
Member, Vaccines & Related Biological Products Advisory Committee (VRBPAC)

FDA Update
Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

ACIP Update
Sara Oliver, MD, MSPH
LCDR, U.S. Public Health Service
Co-Lead, COVID-19 Work Group of the Advisory Committee on Immunization Practices
U.S. Centers for Disease Control and Prevention (ACIP)

Pediatric Vaccine Implementation: Key Considerations for Clinicians
Lisa M. Costello, MD, MPH, FAAP
Assistant Professor and Clerkship Co-director
Division of Pediatric General Medicine
West Virginia University School of Medicine
Immediate Past President, West Virginia Chapter and Member, Committee on State Government Affairs, American Academy of Pediatrics
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
COVID-19 Update

Brendan Jackson, MD, MPH
CDC COVID-19 Response

Where We are Now, Where We are Going

Brendan Jackson, MD, MPH
Principal Deputy Incident Manager
CDC COVID-19 Response

June 25, 2022
COVID-19 Pandemic Situation Update
COVID-19 Surveillance Summary: Cases

- 539,119,771 cumulative confirmed cases globally
- 6,322,311 cumulative deaths

Data as of June 23, 2022
Source: WHO Coronavirus (COVID-19) Dashboard
COVID-19 Community Levels (CCLs)

COVID-19 Community Levels in the United States by County as of June 23, 2022

Time Period: COVID-19 Community Levels were calculated on Thu Jun 23 2022. New COVID-19 cases per 100,000 population (7-day total) are calculated using data from Thu Jun 16 2022 - Wed Jun 22 2022. New COVID-19 admissions per 100,000 population (7-day total) and Percent of inpatient beds occupied by COVID-19 patients (7-day average) are calculated using data from Wed Jun 15 2022 - Tue Jun 21 2022.

Source: CDC COVID Data Tracker (County View)
CCL Trajectory Analysis (5/26/2022 – 6/23/2022)
COVID-19 Surveillance Summary: Hospitalizations and Deaths

- As of June 21, 2022
  - 7-day average of daily new hospitalizations increased 1.0% compared with previous week

- As of June 22, 2022
  - 7-day average of daily death counts decreased 10.4% compared with previous week

New Admissions of Patients with Confirmed COVID-19, United States
August 2020 – June 2022

New Deaths Reported
545

1,010,089 Total Deaths Reported

Peak in New Admissions and Highest 7-Day Moving Average

Daily Change in COVID-19 Death Counts, United States
March 2020 – June 2022

*Note that data starting on June 10, 2020. The trends include deaths reported from Jan 22, 2020.
** The numerator, total of deaths in the last 24 hours, and 7-day average do not include deaths reported in preliminary reports. Preliminary deaths are not reflected in the cumulative national total. The CTD's initial deaths reported methodology, none were reported on Jun 10, 2020, none in the current week, only one in the prior week.
COVID-19 Surveillance Summary: Cases

- As of June 22, 2022
  - 7-day average of daily case counts decreased 5.6% compared with previous week
- How has home testing affected surveillance?

![Daily Change in COVID-19 Case Counts, United States March 2020 – June 2022]

[Graph showing daily change in COVID-19 case counts from March 2020 to June 2022, with peak dates and changes highlighted.]
COVID-19 Wastewater Surveillance

Current SARS-CoV-2 virus levels by site, United States

<table>
<thead>
<tr>
<th>Current virus levels category</th>
<th>Num. sites</th>
<th>% sites</th>
<th>Category change in last 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Site</td>
<td>275</td>
<td>33</td>
<td>1%</td>
</tr>
<tr>
<td>0% to 19%</td>
<td>15</td>
<td>2</td>
<td>- 6%</td>
</tr>
<tr>
<td>20% to 39%</td>
<td>71</td>
<td>9</td>
<td>18%</td>
</tr>
<tr>
<td>40% to 59%</td>
<td>174</td>
<td>21</td>
<td>- 14%</td>
</tr>
<tr>
<td>60% to 79%</td>
<td>232</td>
<td>28</td>
<td>1%</td>
</tr>
<tr>
<td>80% to 100%</td>
<td>63</td>
<td>8</td>
<td>- 30%</td>
</tr>
</tbody>
</table>

Total sites with current data: 830
Total number of wastewater sampling sites: 1033

Source: CDC COVID Data Tracker: Wastewater Surveillance
COVID-19 Variants

- Estimated percentage of COVID-19 variants circulating in the United States as of June 18, 2022
  - Omicron BA.2.12.1: 56.0% of cases
  - Omicron BA.5: 23.5%
  - Omicron BA.4: 11.4%
  - Omicron BA.2: 9.1%

Source: CDC COVID Data Tracker: Variant Proportions
COVID-19 Vaccination: Domestic

- As of June 23, 2022
  - 78.1% of US population has received at least 1 dose
  - 66.9% of US population fully vaccinated
  - 47.3% of fully vaccinated persons have received one additional dose

Source: CDC COVID Data Tracker: Vaccinations in the US
# COVID-19 Boosters

## Primary Series Completion, Booster Dose Eligibility, and Booster Dose Receipt by Age, United States

<table>
<thead>
<tr>
<th>Age Group</th>
<th>US Pop</th>
<th>Fully Vaccinated</th>
<th>1st Booster Eligible</th>
<th>1st Booster Received</th>
<th>2nd Booster Eligible</th>
<th>2nd Booster Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-11 Years</td>
<td>28,744,900</td>
<td>0.52M (29.0%)</td>
<td>5.54M (19.3%)</td>
<td>498k (1.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-17 Years</td>
<td>25,304,508</td>
<td>15.1M (59.0%)</td>
<td>4.07M (16.1%)</td>
<td></td>
<td>37.0M (25.5%)</td>
<td></td>
</tr>
<tr>
<td>18-49 Years</td>
<td>139,753,772</td>
<td>96.2M (65.7%)</td>
<td></td>
<td></td>
<td>52.1M (81.0%)</td>
<td>52.9M (80.0%)</td>
</tr>
<tr>
<td>50-64 Years</td>
<td>63,659,835</td>
<td>52.4M (44.6%)</td>
<td>26.4M (41.3%)</td>
<td>5.12M (8.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65+ Years</td>
<td>54,792,026</td>
<td>50.1M (91.4%)</td>
<td></td>
<td>48.7M (88.9%)</td>
<td>32.8M (59.9%)</td>
<td></td>
</tr>
</tbody>
</table>

Current Priorities, Future Opportunities
Prioritize Health Equity

- Build on successes, learn from failures, ensure that equity remains a priority at all levels of response
- Ensure health equity consideration from the start in planning scientific studies, programmatic activities, guidance updates, etc.
- Understand and address concerns of people with disabilities, strengthen ties to advocacy organizations
- Assist with equitable access to testing and therapeutics
Protect the Vulnerable

- Communicate effective strategies to help protect yourself and others against COVID-19

- Communicate treatment availability for those at higher risk of severe disease

- Sustain use of COVID-19 vaccines to protect the health of individuals and communities

Image Sources: [COVID-19 Vaccine Boosters | CDC](https://www.cdc.gov); [DON’T DELAY: TEST SOON AND TREAT EARLY (cdc.gov)](https://www.cdc.gov)
Incorporate COVID-19 into Routine Public Health Practice

- Planning for sustainability and incorporation of COVID-19 into routine public health practice
- CDC continues to fund and support development of public health emergency response capabilities in health departments
Data Modernization

- Expectations for timely and complete data and analysis have changed from public, media, policy makers, public health practitioners
- Data Modernization Initiative (DMI): Expanding the revolution in data science, analysis, and visualization for public health
Potential Long-Term Behavior Changes?

- Staying home when sick
- Normalization of option for people to use masks use in daily life
- Home testing for COVID-19 and other illnesses
Indoor Air Quality: Next Step in the Sanitary Revolution

- Recognizing and acting on the importance of effective ventilation, filtration, disinfection
- Benefits in reduction of other respiratory infections
- Interactive Ventilation Tool | CDC

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Vaccination in Children Under 5 Years: Re-Cap of Recent Decisions and the Data Underlying Them

Perspectives from VRBPAC

Archana Chatterjee, MD, PhD
CDC/IDSA COVID-19 Clinician Call
June 25, 2022: Perspectives from VRBPAC

Archana Chatterjee, MD, PhD
Dean, Chicago Medical School
Vice President for Medical Affairs, Rosalind Franklin University of Medicine and Science
Highlights from VRBPAC Meeting
June 14-15, 2022

Day 1
➢ Focused on Moderna COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendment, Use of a 2-Dose Primary Series in Children and Adolescents 6 years through 17 Years of Age.
➢ CDC Presentations on:
  ➢ COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents
  ➢ mRNA COVID-19 Vaccine Effectiveness
  ➢ mRNA COVID-19 Vaccine Post Authorization Safety Assessment in Pediatric Age Groups

Day 2
➢ Focused on Moderna COVID-19 Vaccine: Request for EUA Amendment, use of a 2-Dose Primary Series in Infants and Children 6 Months through 5 Years of Age.
➢ Focused on Pfizer-BioNTech COVID-19 Vaccine: Request for EUA Amendment, Use of a 3-Dose Primary Series in Infants and Children 6 Months through 4 Years of Age
## Moderna Pediatric Clinical Trials

<table>
<thead>
<tr>
<th>Dose/regimen:</th>
<th>6-11 years</th>
<th>12-17 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50 µg</td>
<td>100 µg</td>
</tr>
<tr>
<td></td>
<td>Two doses</td>
<td>Two doses</td>
</tr>
<tr>
<td></td>
<td>(0, 28 days)</td>
<td>(0, 28 days)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Type</th>
<th>6-11 years</th>
<th>12-17 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric Study</td>
<td>P204</td>
<td>P203</td>
</tr>
<tr>
<td>mRNA-1273 recipients</td>
<td>3,007</td>
<td>2,486</td>
</tr>
</tbody>
</table>

- Immunobridging to 18-25-year-old participants in P301 (GMT and seroresponse)
  - ✓
  - ✓

- Descriptive efficacy
  - ✓
  - ✓
## Summary of Benefits & Risks (6 through 17 Years)

<table>
<thead>
<tr>
<th>Known and Potential Benefits</th>
<th>Uncertainties in Benefits</th>
<th>Known and Potential Risks</th>
<th>Uncertainties in Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of symptomatic COVID-19, based on:</td>
<td>• Effectiveness against: emerging SARS-CoV-2 variants, long term effects of COVID-19 disease</td>
<td>• Local and systemic reactogenicity</td>
<td>• Safety in certain subpopulations</td>
</tr>
<tr>
<td>• Immunobridging analyses met pre-specified success criteria that allow for inference of vaccine effectiveness for individuals 6-17 years of age</td>
<td>• Effectiveness in: certain populations at higher risk of severe COVID-19, individuals previously infected with SARS-CoV-2</td>
<td>• Lymphadenopathy</td>
<td>• Adverse reactions that are uncommon or that require longer follow-up to be detected</td>
</tr>
<tr>
<td>• Supportive evidence of vaccine efficacy against symptomatic COVID-19 in descriptive analyses</td>
<td>• Duration of protection</td>
<td>• Myocarditis/pericarditis</td>
<td></td>
</tr>
<tr>
<td>• Expectation of greater effectiveness against more severe COVID-19</td>
<td></td>
<td>• Anaphylaxis, and other hypersensitivity reactions</td>
<td></td>
</tr>
</tbody>
</table>
Voting Questions for EUA

1. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (100 μg each dose) outweigh its risks for use in adolescents 12 through 17 years of age?

2. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (50 μg each dose) outweigh its risks for use in children 6 through 11 years of age?
### Moderna Infants & Children Study

<table>
<thead>
<tr>
<th></th>
<th>6-23 months</th>
<th>2-5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose/regimen:</strong></td>
<td>25 µg</td>
<td>25 µg</td>
</tr>
<tr>
<td></td>
<td>Two doses</td>
<td>Two doses</td>
</tr>
<tr>
<td></td>
<td>(0, 28 days)</td>
<td>(0, 28 days)</td>
</tr>
<tr>
<td><strong>Pediatric Study</strong></td>
<td>P204</td>
<td>P204</td>
</tr>
<tr>
<td>mRNA-1273 recipients</td>
<td>1,761</td>
<td>3,031</td>
</tr>
<tr>
<td>Immunobridging to 18-25-year-old participants in P301 (GMC and seroresponse)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Descriptive efficacy</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
## Summary of Benefits and Risks 6 months - 5 years

<table>
<thead>
<tr>
<th>Known and Potential Benefits</th>
<th>Uncertainties in Benefits</th>
<th>Known and Potential Risks</th>
<th>Uncertainties in Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of symptomatic COVID-19, based on:</td>
<td>Effectiveness against: emerging SARS-CoV-2 variants, long term effects of COVID-19 disease</td>
<td>Local and systemic reactogenicity</td>
<td>Safety in certain subpopulations</td>
</tr>
<tr>
<td>• Immunobridging analyses met pre-specified success criteria that allow for inference of vaccine effectiveness for individuals 6 months - 5 years of age</td>
<td>• Effectiveness in: certain populations at higher risk of severe COVID-19, individuals previously infected with SARS-CoV-2</td>
<td>• Lymphadenopathy</td>
<td>• Adverse reactions that are uncommon or that require longer follow-up to be detected</td>
</tr>
<tr>
<td>• Supportive evidence of vaccine efficacy against symptomatic COVID-19 in descriptive analyses</td>
<td>• Duration of protection</td>
<td>• Myocarditis/pericarditis</td>
<td></td>
</tr>
<tr>
<td>• Expectation of greater effectiveness against more severe COVID-19</td>
<td></td>
<td>• Anaphylaxis and other hypersensitivity reactions</td>
<td></td>
</tr>
</tbody>
</table>
Voting Question for EUA

• Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (25 μg each dose) outweigh its risks for use in children 6 months through 5 years of age?
Pfizer C4591007: Amended Phase 2/3 Study Design

6-23 months of age (n= 1776)
2-4 years of age (n= 2750)

Randomized 2:1

BNT162b2

Dose 1
3 weeks

Dose 2
≥8 weeks

Dose 3

Placebo

Dose 1
3 weeks

Dose 2
≥8 weeks

Dose 3
C4591007: Immunobridging Analysis

Comparisons of neutralizing antibody responses to USA_WA1/2020**
### Summary of Benefits & Risks 6 Months – 4 Years

<table>
<thead>
<tr>
<th>Known and Potential Benefits</th>
<th>Uncertainties in Benefits</th>
<th>Known and Potential Risks</th>
<th>Uncertainties in Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of symptomatic COVID-19, based on:</td>
<td>• Effectiveness against: emerging SARS-CoV-2 variants, long term effects of COVID-19</td>
<td>• Local and systemic reactogenicity</td>
<td>• Safety in certain subpopulations</td>
</tr>
<tr>
<td>• Immunobridging analyses met pre-specified success criteria that allow for inference of vaccine effectiveness for individuals 6 months- 4 years of age</td>
<td>• Effectiveness in: certain populations at higher risk of severe COVID-19, individuals previously infected with SARS-CoV-2</td>
<td>• Myocarditis/pericarditis</td>
<td>• Adverse reactions that are uncommon or that require longer follow-up to be detected</td>
</tr>
<tr>
<td>• Preliminary evidence of vaccine efficacy against COVID-19 in descriptive analyses</td>
<td>• Duration of protection</td>
<td>• Lymphadenopathy</td>
<td></td>
</tr>
<tr>
<td>• Expectation of greater effectiveness against more severe COVID-19</td>
<td></td>
<td>• Anaphylaxis and other hypersensitivity reactions</td>
<td></td>
</tr>
</tbody>
</table>
Voting Question for EUA

• Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine, when administered as a three-dose series (3 mcg each dose), outweigh its risks for use in infants and children 6 months through 4 years of age?
Vaccination in Children Under 5 Years: Re-Cap of Recent Decisions and the Data Underlying Them

FDA Update

Peter Marks, MD, PhD
Pediatric COVID-19 Vaccines

Peter Marks, MD, PhD
IDSA/CDC Call
June 25, 2022
COVID-19 Vaccines in Young Children

• Special considerations in children 5 years and younger
  – Determination of appropriate dosage and number of doses
  – Duration and number of children for safety follow-up
  – Benefit-risk considerations

• Trials completed is several thousand children with immunogenicity determined in several hundred
  – Moderna 2-dose regimen
  – Pfizer-BioNTech 3-dose regimen
### Moderna 6 mo through 5 yrs

2 dose regimen 25 mcg (1/4 adult dose) days 1, 28

<table>
<thead>
<tr>
<th>Parameter</th>
<th>6 mo – 2 yrs</th>
<th>6 mo – 2 yrs</th>
<th>2 yrs – 5 yrs</th>
<th>2 yrs – 5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine</td>
<td>Placebo</td>
<td>Vaccine</td>
<td>Placebo</td>
</tr>
<tr>
<td>Safety Dose 2</td>
<td>Local Redness</td>
<td>13.5%</td>
<td>3.8%</td>
<td>8.8%</td>
</tr>
<tr>
<td></td>
<td>Fever</td>
<td>14.6%</td>
<td>8.3%</td>
<td>16.9%</td>
</tr>
<tr>
<td>Immunogenicity (GMTR)</td>
<td></td>
<td></td>
<td>1.3 (95% CI 1.1, 1.5)</td>
<td>1.0 (95% CI 0.98, 1.27)</td>
</tr>
<tr>
<td>Effectiveness</td>
<td></td>
<td></td>
<td>31.5% (95% CI -27.7, 62.0)</td>
<td>46.4% (95% CI 19.8, 63.8)</td>
</tr>
</tbody>
</table>

GMTR compared with 18 to 25 yrs.; Efficacy cases n = 37:18, 71:43 with 3:1 randomization
Pfizer-BioNTech 6 mo through 4 yrs

3 dose regimen 3 mcg (1/10 adult dose) days 1, 21, 81

<table>
<thead>
<tr>
<th>Parameter</th>
<th>6 mo – 2 yrs Vaccine</th>
<th>6 mo – 2 yrs Placebo</th>
<th>2 yrs – 5 yrs Vaccine</th>
<th>2 yrs – 5 yrs Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Dose 3</td>
<td>Local Redness</td>
<td>7.1%</td>
<td>5.3%</td>
<td>10.9%</td>
</tr>
<tr>
<td></td>
<td>Fever</td>
<td>6.8%</td>
<td>5.9%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>6 mo – 2 yrs</th>
<th>2 yrs – 5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunogenicity (GMTR)</td>
<td>1.19 (95% CI 1.00, 1.42)</td>
<td>1.30 (95% CI 1.13, 1.50)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>6 mo – 2 yrs</th>
<th>2 yrs – 5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>82.3% (95% CI -8.0, 98.3)</td>
<td>75.5% (95% CI -370.1, 99.6)</td>
</tr>
</tbody>
</table>

GMTR compared with 16 to 25 yrs.; Efficacy cases n = 2:5, 1:2 with 2:1 randomization
Vaccination in Children Under 5 Years: Re-Cap of Recent Decisions and the Data Underlying Them

ACIP Update

Sara Oliver, MD, MSPH
Recommendations for mRNA COVID-19 vaccines in children and adolescents

Sara Oliver, MD, MSPH
Summary

- Since the beginning of the COVID-19 pandemic:
  - Among U.S. children ages 6 months – 4 years of age, there have been
    - Over 2 million cases
    - Over 20,000 hospitalizations
    - Over 200 deaths
  - Among U.S. children ages 5 – 17 years of age, there have been
    - Over 10 million cases
    - Over 45,000 hospitalizations
    - Over 600 deaths
- COVID-19 can cause severe disease and death among children and adolescents, including those without underlying medical conditions
- Future surges will continue to impact children, with unvaccinated children remaining at higher risk of severe outcomes
**ACIP interpretation:**
mRNA COVID-19 vaccines in young children

- mRNA COVID-19 vaccine clinical trials in young children both conducted during Omicron predominance, but different months and incidence levels
- **Efficacy estimates** for these two vaccines **cannot be directly compared**
- Both vaccines met non-inferiority criteria for neutralizing antibody levels
- Clinical trials were not powered to detect efficacy against severe disease in young children, but similar patterns in this age group are expected to what is seen in everyone ages 5 years and older
- Post-authorization effectiveness studies can help determine subsequent timing and need of **boosters**
  - Immunocompromised children may also need additional doses for optimal protection
Summary
mRNA COVID-19 vaccines in children and adolescents

- As with all other age groups, priority is **vaccination** of unvaccinated individuals

- **18.7 million** children ages 6 months–4 years now eligible

- **25 million** unvaccinated children and adolescents ages 5–11 and 12–17 years

- Benefits outweigh risks for mRNA COVID-19 vaccines in all ages: receipt of **primary series** continues to be the **safest** way to prevent serious COVID-19
ACIP Recommendation

A **two-dose** Moderna COVID-19 vaccine series (25µg) is recommended for children ages **6 months –5 years**, under the EUA issued by FDA

Two doses of 25µg Moderna COVID-19 vaccine, 28-days apart

---

A **three-dose** Pfizer-BioNTech COVID-19 vaccine series (3µg each) is recommended for children ages **6 months – 4 years**, under the EUA issued by FDA

Three doses of 3µg Pfizer-BioNTech COVID-19 vaccine 21 days and at least 8 weeks apart
ACIP Recommendation

A **two-dose** Moderna COVID-19 vaccine series (50µg) is recommended for children ages **6–11 years**, under the EUA issued by FDA.

A **two-dose** Moderna COVID-19 vaccine series (100µg) is recommended for adolescents ages **12 – 17 years**, under the EUA issued by FDA.
# Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age Group</th>
<th>Dose 1 (primary)</th>
<th>Dose 2 (primary)</th>
<th>Dose 3 (booster)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moderna</strong> (6 months–17 years)</td>
<td></td>
<td>Dose 1</td>
<td>4-8 weeks</td>
<td>Dose 2</td>
</tr>
<tr>
<td><strong>Pfizer-BioNTech</strong> (6 months–4 years)</td>
<td></td>
<td>Dose 1</td>
<td>3-8 weeks</td>
<td>Dose 2</td>
</tr>
<tr>
<td><strong>Pfizer-BioNTech</strong> (5 years–17 years)</td>
<td></td>
<td>Dose 1</td>
<td>3-8 weeks</td>
<td>Dose 2</td>
</tr>
</tbody>
</table>

- At least 8 weeks
- 4-8 weeks
## Pediatric Schedule: People Who **ARE** Moderately or Severely Immunocompromised

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Age Range</th>
<th>Dose 1 (primary)</th>
<th>Dose 2 (primary)</th>
<th>Dose 3 (primary)</th>
<th>Dose 4 (booster)</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>(6 months–17 years)</td>
<td>4 weeks</td>
<td>3 weeks</td>
<td>3 weeks</td>
<td></td>
<td>At least 8 weeks</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>(6 months–4 years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 weeks</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>(5 years–11 years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>At least 3 months</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>(12 years–17 years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>At least 4 months</td>
</tr>
</tbody>
</table>

---

The diagrams show the scheduling for different age ranges, with the primary doses and booster doses indicated along with the recommended intervals between doses.
Considerations for Extended Interval Between Dose 1 & 2

- Immunocompromised
- High risk for severe disease
- Household members with high risk for severe disease
- High COVID-19 community levels

- Reduced myocarditis risk
- Adolescent and young adult males
- Optimize vaccine effectiveness
## Moderna COVID-19 Vaccine Products

<table>
<thead>
<tr>
<th>Authorized Age group</th>
<th>6 months–5 years (primary series)</th>
<th>• 6–11 years (primary series)</th>
<th>• 12 years and older (primary series)</th>
<th>• 18 years and older (booster doses)</th>
<th>• 18 years and older (booster doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial cap color</td>
<td>Dark blue</td>
<td>Dark blue</td>
<td>Red</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label border color</td>
<td>Magenta</td>
<td>Purple</td>
<td>Light blue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose (mRNA concentration)</td>
<td>25 mcg</td>
<td>50 mcg</td>
<td>100 mcg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection volume</td>
<td>0.25 mL</td>
<td>0.5 mL</td>
<td>0.5 mL (primary, age 12+); 0.25 mL (booster, age 18+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dilution required</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doses per vial</td>
<td>10</td>
<td>5</td>
<td>Maximum of 11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Moderna COVID-19 Vaccine Product for Ages 6–11 Years

Labeled for “BOOSTER DOSES ONLY” but is authorized for:

- Primary doses in children ages 6–11 years
- Booster doses in adults ages 18 years and older
# Pfizer-BioNTech COVID-19 Vaccine Products

<table>
<thead>
<tr>
<th>Authorized for ages</th>
<th>Product for ages 6 months–4 years</th>
<th>Product for ages 5–11 years</th>
<th>Product for ages 12 years and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial cap color</td>
<td>Maroon</td>
<td>Orange</td>
<td>Gray</td>
</tr>
<tr>
<td>Dose (mRNA concentration)</td>
<td>3 mcg</td>
<td>10 mcg</td>
<td>30 mcg</td>
</tr>
<tr>
<td>Injection volume</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>Dilution required</td>
<td>Yes—2.2 mL</td>
<td>Yes—1.3 mL</td>
<td>No</td>
</tr>
<tr>
<td>Doses per vial</td>
<td>10 (after dilution)</td>
<td>10 (after dilution)</td>
<td>6</td>
</tr>
</tbody>
</table>
Pfizer-BioNTech COVID-19 Vaccine Product for Ages 6 Months–4 Years

Vaccine may be discarded **12 hours** after dilution rather than **6 hours**.

Vial label states Age 2y to <5y but can be used in children ages 6 months–4 years.
Vaccine Dosage

- Children should receive the age-appropriate vaccine product and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.

- If a child moves from a younger age group to an older age group (e.g., moves from age 11 years to age 12 years) during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.
Children who turn from age 4 to 5 years
Recommended
Pfizer-BioNTech COVID-19 vaccine

5th birthday

Dose 1:
Maroon cap, 3 mcg
0.2mL

3-8 weeks

Dose 2:
Orange cap, 10 mcg
0.2mL

8 weeks

Dose 3:
Orange cap, 10 mcg
0.2mL
Children who turn from age 4 to 5 years

Recommended Pfizer-BioNTech COVID-19 vaccine

Dose 1: Maroon cap, 3 mcg 0.2mL

3-8 weeks

Dose 2: Maroon cap, 3 mcg 0.2mL

8 weeks

Dose 3: Orange cap, 10 mcg 0.2mL

5th birthday
Children who turn from age 4 to 5 years
Allowed (not an administration error)
Pfizer-BioNTech COVID-19 vaccine

Dose 1:
Maroon cap, 3 mcg

Dose 2:
Orange cap, 10 mcg
---or---
Maroon cap, 3 mcg

Dose 3:
Orange cap, 10 mcg
---or---
Maroon cap, 3 mcg
Children who turn from age 5 to 6 years
Recommended
Moderna COVID-19 vaccine

Dose 1:
- Dark blue cap, magenta label border
- 25mcg
- 0.25mL

Dose 2:
- Dark blue cap, purple border
- 50mcg
- 0.5mL

6th birthday

4-8 weeks
Children who turn from age 5 to 6 years
Allowed (not an administration error)
Modern COVID-19 vaccine

6th birthday

Dose 1:
Dark blue cap, magenta label border
---or---
Dark blue cap, purple border

4-8 weeks

Dose 2:
Dark blue cap, magenta label border
---or---
Dark blue cap, purple border
Children who turn from age 11 to 12 years

**Recommended**

Modernza COVID-19 vaccine

**Dose 1:**
- Dark blue cap, purple border
- 50mcg
- 0.5mL

4-8 weeks

**Dose 2:**
- Red cap, light blue border
- 100mcg
- 0.5mL

12\textsuperscript{th} birthday
Children who turn from age 11 to 12 years Allowed (not an administration error) Moderna COVID-19 vaccine

**Dose 1:**
- Dark blue cap, purple border
- Red cap, light blue border

---or---

**Dose 2:**
- Dark blue cap, purple border
- Red cap, light blue border

4-8 weeks

12th birthday
Administration

- Existing guidance applies to children and adolescents

**Coadministration:** COVID-19 vaccines *may be administered* without regard to timing of other vaccines
  - Considerations included in the interim clinical considerations

**Interchangeability:** COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series
Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should receive a third dose of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose primary series.
Mixed Series For Children Ages 6 months–4 Years

- **Scenario 1:**

  Dose 1: Pfizer-BioNTech
  Maroon cap, 3 mcg

  4-8 weeks

  Dose 2: Moderna
  Dark blue cap, magenta label border, 25 mcg

  8 weeks

  --or--

  Dose 3: Pfizer-BioNTech
  Maroon cap, 3 mcg

  --or--

  Moderna
  Dark blue cap, magenta label border, 25 mcg
Mixed Series For Children Ages 6 months–4 Years

Scenario 2:

- **Dose 1:** Moderna
  - Dark blue cap, magenta label border
  - 25 mcg

- **Dose 2:** Pfizer-BioNTech
  - Maroon cap, 3 mcg

- **Dose 3:** Either
  - Pfizer-BioNTech
    - Maroon cap, 3 mcg
  - Moderna
    - Dark blue cap, magenta label border
    - 25 mcg

4-8 weeks → 8 weeks → --or--
Potential Vaccine Administration Errors

- More opportunities for errors with:
  - More products
  - Products not labeled for the indicated age group
  - New pediatric providers that may be unfamiliar with COVID-19 vaccines

- Most likely errors with this context:
  - Incorrect product and/or dose volume, resulting in a higher-than-authorized dose
  - Incorrect product and/or dose volume, resulting in a lower-than-authorized dose
  - Correct dose from an incorrect product
  - Vaccine administered past beyond-use date
Preventing Vaccine Administration Errors

- Clinical guidance for errors:
  https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c

- Handout:
  https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf
Interim Clinical Considerations

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- FAQs for the Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html
Clinical Resources

- US COVID-19 Vaccine Product Information:  
  https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

- Age transition job aids  
Resources for Vaccine Recipient Education

- Recipient Education: https://www.cdc.gov/vaccines/covid-19/hcp/index.html
Pediatric Vaccine Implementation: Key Considerations for Clinicians

Lisa M. Costello, MD, MPH, FAAP
Pediatric COVID-19 Vaccine Implementation: Key Considerations for Clinicians

June 25, 2022

Lisa M. Costello, MD, MPH, FAAP
Immediate Past President, AAP West Virginia Chapter
Member, AAP Committee on State Government Affairs (COSGA)
No financial disclosures
HOPE FOR THE FUTURE: COVID-19 VACCINATION FOR CHILDREN 6 MONTHS AND OLDER

American Academy of Pediatrics Applauds CDC Approval of Safe, Effective COVID-19 Vaccines for Children Ages 6 Months and Older

IT'S HERE—Today, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended two COVID-19 vaccines: one for children ages 6 months through 4 years and one for ages 4 through 15 years. The American Academy of Pediatrics (AAP) supports this recommendation and encourages pediatricians to promote vaccination and give COVID-19 vaccines. The AAP urges families to check with their pediatrician and community health care providers about how to get their children vaccinated, pending a final recommendation from the CDC.

Speaking at the ACIP meeting, pediatrician Vivienne “Bonnie” Maldonado, MD, FAAP, chair of the AAP Committee on Infectious Diseases, emphasized the importance of these vaccines for the youngest members of our community, who have existed the longest for this protection.

"Pediatricians know the power of vaccines to protect infants, children, adolescents and entire communities against deadly and debilitating infectious diseases," Dr. Maldonado said. "We've successfully immunized millions of children and adolescents to protect them from COVID-19. Families with infants and toddlers need and deserve the same chance to protect their children from this virus."

Authorization of the Moderna and Pfizer-BioNTech vaccines for children ages 6 months and older will extend the protection of immunization to the last segment of our population awaiting protection. More work remains to vaccinate older children and adolescents, as well. As of June 8, more than 25 million children ages 2 to 11 have received two doses of COVID vaccine. Another 25 million in the age group have yet to receive any doses.

"We must not let up in our efforts to make sure all families can benefit from the protection of these vaccines," said AAP President Maisha I. Satia-Allen, MD, FAAP. "Pediatricians are ready to have these conversations, and parents and caregivers should feel comfortable bringing their questions to their trusted pediatrician to have their questions addressed."

Immediately after the ACIP vote to recommend the Moderna and Pfizer-BioNTech COVID-19 vaccines for children ages 6 months and older, the AAP published its updated recommendations for COVID-19 vaccine, including a strong recommendation for children in this age group to receive the vaccine pending the final decision by the CDC. The AAP recommends COVID-19 vaccination for all children and adolescents 6 months of age and older who do not have contraindications using a vaccine authorized for use for their age. The AAP encourages all states to work with pediatricians and practices to make accessing COVID-19 vaccine as simple as possible.

The updated AAP policy statement will be published online in Pediatrics and also can be found by visiting the AAP.org website.

More resources:
- HealthyChildren.org: What Should Parents Know About the COVID Vaccine for Kids Under 5?
- AAP News: Critical updates on COVID-19
- AAP News: COVID-19 collection
THE CHALLENGES AHEAD

Access  Communication  Education
Proportion of US Children Ages 12-17 Who Received the Initial Dose of the COVID-19 Vaccine, by State of Residence

Proportion of US Children Ages 5-11 Who Received the Initial Dose of the COVID-19 Vaccine, by State of Residence

Source: AAP analysis of data series titled "COVID-19 Vaccinations in the United States, Jurisdiction", CDC COVID-19 Data Tracker (URL: https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-In-the-United-States-Jurisdiction/unsk-b7f5). Check state web sites for additional or more recent information.
HELP PROMOTE A CULTURE OF VACCINATION

• Emphasize your state’s track record of success in delivering immunizations to children
• Talk about childhood immunizations as the norm
• Emphasize safety—child safety, school safety, community safety
• Improve access and availability of vaccines
• Cost savings attributed to childhood immunizations are immense—remind the public of this fact
• Engage trusted voices—pediatricians are here to help
• Offer education and communication resources
COVID-19 Shots are the Best Way to Protect Against COVID-19

Children 6 months of age and older are now eligible to get vaccinated against COVID-19.
Joint Interagency Task Force on COVID-19
June 20, 2022

Training for COVID-19 Vaccines:
Pfizer BioNTech ages 6 month through 4 years
Moderna* ages 6 months through 5 years

Krista D. Capehart, PharmD, MS, BCACP, FAPhA
WV Board of Pharmacy
WVU School of Pharmacy

Lisa M. Costello, MD, MPH, FAAP
WV Chapter American Academy of Pediatrics
WVU School of Medicine

VACCINATE.WV.GOV
#CommunityImmunityWV

*Note: The ACIP will meet June 23, 2022 to discuss recommendations for Moderna COVID-19 vaccine for ages 6 through 17 years. Information forthcoming.
Join Us for Our Upcoming Webinar:

COVID-19 Vaccination of Children
6 Months of Age and Up
June 29, 2022 • 12:00 PM - 1:00 PM

Speakers:

Krista D. Capehart, PharmD, MS, BCACP, FAPhA is a Clinical Professor in the Department of Clinical Pharmacy and Director of the Wigner Institute for Advanced Pharmacy Practice, Education and Research at West Virginia University School of Pharmacy. She is also the Director of Professional and Regulatory Affairs at the West Virginia Board of Pharmacy. More details here.

Jacob T. Kilgore, MD, MPh, FAAP, is an Assistant Professor in the Department of Pediatrics, Division of Pediatric Infectious Diseases at the Marshall University Joan C. Edwards School of Medicine (MU-JCESOM). More details here.
AAP State Chapters: Pulling in the Same Direction

https://www.aap.org/en/community/chapter-websites/
MORE FROM THE AAP

https://www.healthychildren.org/


Contact stgov@aap.org for more information on connecting with the AAP chapter in your state. Reach me at costello.lisa@gmail.com.
Q&A/Discussion
Selected Resources

Dr. Jackson
• Slide 7 - https://covid19.who.int/
• Slide 8 - https://covid.cdc.gov/covid-data-tracker/#county-view
• Slide 12 - https://covid.cdc.gov/covid-data-tracker/#wastewater-surveillance
• Slide 13 - https://covid.cdc.gov/covid-data-tracker/#variant-proportions
• Slide 14 - https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total
• Slide 15 - https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends

Dr. Oliver
• Slide 69 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#appendix-c
• Slide 69 - https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf
• Slide 70 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
• Slide 70 - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html
• Slide 71 - https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
• Slide 71 - https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Child-Age-Transition-508.pdf
• Slide 72 - https://www.cdc.gov/vaccines/covid-19/hcp/index.html
• Slide 72 - https://www.cdc.gov/vaccines/covid-19/planning/children.html
Selected Resources

Dr. Costello
• Slide 84 - https://www.aap.org/en/community/chapter-websites/
• Slide 85 - https://www.healthychildren.org/English/Pages/default.aspx

Program Links:
• This webinar is being recorded and can be found with the slides online at https://www.id society.org/cliniciancalls
• Vaccine FAQ: https://www.id society.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/
An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

Specialty Society Collaborators

American Academy of Family Physicians
American Academy of Pediatrics
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
@RealTimeCOVID19
#RealTimeCOVID19
CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?
- Clinicians who have questions about the clinical management of COVID-19

WHAT?
- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?
- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form

cdc.gov/coronavirus
We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at www.idsociety.org/cliniciancalls

-- library of all past calls available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)