Updates to Interim Clinical Considerations for Use of COVID-19 Vaccines

Evelyn Twentyman, MD MPH
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Overview of implications
Implications of the new recommendations

- Simple and singular for most
- Flexible for people at higher risk
- Customized recommendations for young children
Implications of the new recommendations

- Simple and singular for most
- Flexible for people at higher risk
- Customized recommendations for young children
Previous recommendations for people aged ≥6 years without immunocompromise

People ages 6 through 11 years

Modern or Pfizer-BioNTech

Primary

3-8 weeks (Pfizer) or 4-8 weeks (Moderna)

Primary

At least 2 months

Bivalent mRNA booster†

People ages 12 years and older

Moderna, Novavax, or Pfizer-BioNTech

Primary

3-8 weeks (Novavax, Pfizer) or 4-8 weeks (Moderna)

Primary

At least 2 months

Bivalent mRNA booster†

People ages 18 years and older who previously received Janssen primary series dose§

Primary

At least 2 months

Bivalent mRNA booster†

---

* People ages 6 months–4 years who previously completed a 3-dose monovalent Pfizer-BioNTech primary series are authorized to receive 1 bivalent Pfizer-BioNTech booster dose at least 2 months after completion of the monovalent primary series.

† For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

§ A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.

†† Janssen COVID-19 Vaccine should only be used in certain limited situations. See https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a
New recommendations for people aged ≥6 years without immunocompromise who have not yet received a bivalent mRNA dose
New recommendations for people aged ≥6 years without immunocompromise who have not yet received a bivalent mRNA dose, regardless of COVID-19 vaccination history

- ≥1 monovalent Moderna dose
- ≥1 monovalent Pfizer-BioNTech dose
- ≥1 monovalent Novavax dose
- ≥1 monovalent Janssen dose
- No COVID-19 vaccine doses

One bivalent mRNA dose
New recommendations for aged ≥6 years without immunocompromise who have already received a bivalent mRNA dose

One bivalent mRNA dose

Vaccination is complete. No doses are indicated at this time.
Implications of the new recommendations

- Simple and singular for most

- Flexible for people at higher risk

- Customized recommendations for young children
Flexible for people at higher risk of severe COVID-19: People aged ≥65 years who have not yet received a bivalent mRNA dose

One bivalent mRNA dose → Optional additional bivalent mRNA dose

At least 4 months
Flexible for people at higher risk of severe COVID-19: People aged ≥65 years who have already received a bivalent mRNA dose

One bivalent mRNA dose → Optional additional bivalent mRNA dose

At least 4 months
New flexibility for people at higher risk of severe COVID-19: People aged ≥6 years with immunocompromise* who have already received a bivalent mRNA dose

One bivalent mRNA dose → Optional additional bivalent mRNA dose → Additional bivalent mRNA doses as needed

- Stem cell transplant
- CAR-T therapy
- B-cell depletion
- Others

*Including those with imminent immunocompromise (e.g., prior to organ transplant; other causes.)
Implications of the new recommendations

- Simple and singular for most
- Flexible for people at higher risk
- **Customized recommendations for young children**
Transitioning from the monovalent to the bivalent era for children without immunocompromise aged 6 months – 4 years

Doses previously recommended:

**Moderna:**
- 2 monovalent primary series doses +
- 1 bivalent booster dose

**Pfizer:**
- 2 or 3 monovalent primary series doses +
- 1 bivalent primary series dose

Doses now recommended:

Customized by COVID-19 vaccination history such that all children receive:
- At least 2 vaccine doses in total
  - including
- At least 1 bivalent dose
COVID-19 vaccination algorithm for people without immunocompromise, ages 6 months–4 years, mRNA vaccines April 2023*

COVID-19 vaccination status April 2023

- Unvaccinated

Previously received vaccine(s)

- 1 dose monovalent Moderna
- 2 doses monovalent Moderna
- 2 doses monovalent Moderna and 1 dose bivalent Moderna
- 1 dose monovalent Pfizer-BioNTech
- 2 doses monovalent Pfizer-BioNTech
- 3 doses monovalent Pfizer-BioNTech

Number of doses indicated, by manufacturer

- 2 doses bivalent Moderna
- 3 doses bivalent Pfizer-BioNTech
- 1 dose bivalent Moderna
- 2 doses bivalent Pfizer-BioNTech
- 1 dose bivalent Pfizer-BioNTech

Vaccination complete.

*To see product-specific doses and intervals of administration, see Table 1 and 2 forthcoming in Interim Clinical Considerations, forthcoming.
Transitioning from the monovalent to the bivalent era for children without immunocompromise aged 5 years

Doses previously recommended:

Moderna:
- 2 monovalent primary series doses +
- 1 bivalent booster dose

Pfizer:
- 2 or 3 monovalent primary series doses +
- 1 bivalent primary series dose

Doses now recommended:

Customized so that Moderna recipients receive:
- At least 2 vaccine doses in total including
- At least 1 bivalent dose

And Pfizer recipients receive:
- At least 1 bivalent dose
COVID-19 vaccination algorithm for people without immunocompromise, age 5 years, mRNA vaccines April 2023*

- **Unvaccinated**

- **Vaccinated**
  - 1 or more doses monovalent Moderna
  - 1 or more doses monovalent Pfizer-BioNTech
  - 2 doses monovalent Moderna and 1 dose bivalent mRNA
  - Any doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech

*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming*
Stay Up to Date with COVID-19 Vaccines

- Adults and children aged 6 years and older are up to date with COVID-19 vaccines if they got a bivalent (updated) COVID-19 vaccine.

- Children 6 months through 5 years of age who received the Pfizer-BioNTech COVID-19 vaccine are up to date if:
  - They are 6 months to 4 years of age and got at least 3 COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose.
  - They are 5 years of age and got at least 1 bivalent (updated) COVID-19 vaccine dose.

- Children 6 months through 5 years of age who got the Moderna COVID-19 vaccine are up to date if they got at least two Moderna COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose.

- You may be eligible for additional COVID-19 vaccine doses if:
  - You are 65 years of age and older and got your first bivalent (updated) COVID-19 vaccine booster 4 or more months ago.
  - You are moderately or severely immunocompromised and received a bivalent (updated) COVID-19 vaccine booster 2 or more months ago.

- If you are unable or choose not to get a recommended bivalent mRNA vaccine, you will be up to date if you got the Novavax COVID-19 vaccine doses approved for your age group.
Implications for vaccine providers
Fewer COVID-19 Vaccine Products in Use

Manufacturer | Products Previously in Use | Products Now in Use
---|---|---
Moderna | | ।
Pfizer-BioNTech | Bivalent Bivalent | Bivalent Bivalent
Novavax | । | ।
Janssen | । | ।

All remaining Janssen vaccine doses expire by May 6th 2023
Additional help for providers is on the way

- CDC’s Interim Clinical Considerations for Use of Authorized COVID-19 Vaccines will be updated with comprehensive tables of vaccine doses and dosages indicated
  - For each age group
  - By history of COVID-19 vaccines received, for children ages 6 months through 5 years

- Revision of clinical guidance materials is underway

- COCA Call to be held May 11th, 2023*

*Please visit https://emergency.cdc.gov/coca/ for complete details
Implications for public health
Bivalent COVID-19 vaccine coverage is low.

16.7% of the total U.S. population has received a bivalent COVID-19 vaccine.

20.2% of adults aged ≥18 years in the U.S. have received a bivalent COVID-19 vaccine.

COVID-19 Data Tracker, last updated April 13, 2023, [CDC COVID Data Tracker: Vaccinations in the US](https://covid.cdc.gov/covid-data-tracker/)
Bivalent COVID-19 vaccine coverage generally decreases with decreasing age.

Bivalent COVID-19 Vaccination Coverage by Age

- <2 years: 5%
- 2–4 years: 8%
- 5–11 years: 7%
- 12–17 years: 12%
- 18–24 years: 22%
- 25–49 years: 43%
- 50–64 years: 22%
- > 65 years: 43%

Bivalent COVID-19 vaccine coverage is lower among Black, non-Hispanic, Hispanic/Latino, and Native Hawaiian or Other Pacific Islander.

### Bivalent COVID-19 Vaccination Coverage by Race/Ethnicity

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI/AN, NH</td>
<td>15%</td>
</tr>
<tr>
<td>Asian, NH</td>
<td>22%</td>
</tr>
<tr>
<td>Black, NH</td>
<td>9%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>9%</td>
</tr>
<tr>
<td>Multiracial, NH</td>
<td>24%</td>
</tr>
<tr>
<td>NHOPI, NH</td>
<td>12%</td>
</tr>
<tr>
<td>White, NH</td>
<td>17%</td>
</tr>
</tbody>
</table>
Bivalent COVID-19 vaccine coverage is lower among those with lower income.

Bivalent COVID-19 vaccine coverage by income among adults aged ≥18 years

- Below poverty: 27%
- Above poverty, income <$75K: 29%
- Above poverty, income >$75K: 39%

Bivalent COVID-19 vaccine coverage is lower among those without health insurance.
COVID-19 vaccines continue to be the **most effective tool** we have to prevent serious illness, hospitalization and death from COVID-19

- Uptake of the updated (bivalent) COVID-19 vaccines is not yet equitable, and remains generally low

**Simple recommendations** are easier to communicate, which may improve vaccine uptake

CDC is continuing to work toward **additional materials** for vaccine providers, clinicians and the general public to make it easy for everyone to get up to date and **stay up to date** with COVID-19 vaccines
Acknowledgments

- Sara Oliver
- Hannah Rosenblum
- Mary Chamberland
- Susan Goldstein
- Elisha Hall
- JoEllen Wolicki
- Katherine Fleming-Dutra
- Ruth Link-Gelles
- Monica Godfrey
- Danielle Moulia
- Megan Wallace
- Lauren Roper
- Amadea Britton
- Sarah Meyer
- Julianne Gee
- Heather Scobie
- Sierra Scarbrough
- Yvonne Bolen
- Jefferson Jones
- Noelle Molinari
- Aron Hall
- Barbara Mahon
- Data Analytics and Visualization Task Force
- Coronavirus and other Respiratory Viruses Division
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases
COVID-19 vaccination algorithm for people who are NOT moderately or severely immunocompromised, age 6 years and older, mRNA vaccines April 2023*

*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming.

**People ages 65+ have the option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine.
Tables
<table>
<thead>
<tr>
<th>COVID-19 vaccination history</th>
<th>Bivalent vaccine</th>
<th>Number of bivalent doses indicated</th>
<th>Dosage (mL/ug)</th>
<th>Vaccine vial cap and label colors</th>
<th>Interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>Moderna __<em><strong>or</strong></em></td>
<td>2</td>
<td>0.25 mL/25 ug</td>
<td>Dark blue cap; gray label border</td>
<td>Dose 1 and Dose 2: 4–8 weeks</td>
</tr>
<tr>
<td></td>
<td>Pfizer BioNTech</td>
<td>3</td>
<td>0.2 mL/3 ug</td>
<td>Maroon</td>
<td>Dose 1 and Dose 2: 3–8 weeks Dose 2 and dose 3: At least 8 weeks</td>
</tr>
<tr>
<td>1 dose monovalent Moderna</td>
<td>Moderna</td>
<td>1</td>
<td>0.25 mL/25 ug</td>
<td>Dark blue cap; gray label border</td>
<td>4-8 weeks after monovalent dose</td>
</tr>
<tr>
<td>2 doses monovalent Moderna</td>
<td>Moderna</td>
<td>1</td>
<td>0.2 mL/10 ug</td>
<td>Dark pink cap; yellow label border</td>
<td>At least 8 weeks after last monovalent dose</td>
</tr>
<tr>
<td>2 doses monovalent Moderna  and 1 dose bivalent Moderna</td>
<td>NA; previously received 1 bivalent vaccine dose</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>1 dose monovalent Pfizer-</td>
<td>Pfizer BioNTech</td>
<td>2</td>
<td>0.2 mL/3 ug</td>
<td>Maroon</td>
<td>Dose 1: 3–8 weeks after monovalent dose Dose 1 and Dose 2: At least 8 weeks</td>
</tr>
<tr>
<td>BioNTech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 doses monovalent Pfizer-</td>
<td>Pfizer BioNTech</td>
<td>1</td>
<td>0.2 mL/3 ug</td>
<td>Maroon</td>
<td>At least 8 weeks after last monovalent dose</td>
</tr>
<tr>
<td>BioNTech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 doses monovalent Pfizer-</td>
<td>Pfizer BioNTech</td>
<td>1</td>
<td>0.2 mL/3 ug</td>
<td>Maroon</td>
<td>At least 8 weeks after last monovalent dose</td>
</tr>
<tr>
<td>BioNTech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 doses monovalent Pfizer-</td>
<td>NA; previously received 1 bivalent vaccine dose</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>BioNTech and 1 dose bivalent Pfizer-BioNTech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19 vaccination history</td>
<td>Bivalent vaccine</td>
<td>Number of bivalent doses indicated</td>
<td>Dosage (mL/ug)</td>
<td>Vaccine vial cap and label colors</td>
<td>Interval between doses</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------</td>
<td>-----------------------------------</td>
<td>----------------</td>
<td>----------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>Moderna <em><strong>or</strong></em></td>
<td>2</td>
<td>0.25 mL/25 ug</td>
<td>Dark blue cap; gray label border</td>
<td>Dose 1 and Dose 2: 4–8 weeks</td>
</tr>
<tr>
<td></td>
<td>Pfizer BioNTech</td>
<td></td>
<td>0.2 mL/10 ug</td>
<td>Orange</td>
<td></td>
</tr>
<tr>
<td>1 dose monovalent Moderna</td>
<td>Moderna <em><strong>or</strong></em></td>
<td>1</td>
<td>0.25 mL/25 ug</td>
<td>Dark blue cap; gray label border</td>
<td>4–8 weeks after monovalent dose</td>
</tr>
<tr>
<td></td>
<td>Pfizer BioNTech</td>
<td></td>
<td>0.2 mL/10 ug</td>
<td>Orange</td>
<td>At least 8 weeks after monovalent dose</td>
</tr>
<tr>
<td>2 doses monovalent Moderna</td>
<td>Moderna <em><strong>or</strong></em></td>
<td>1</td>
<td>0.2 mL/10 ug</td>
<td>Dark pink cap; yellow label border</td>
<td>At least 8 weeks after last monovalent dose</td>
</tr>
<tr>
<td></td>
<td>Pfizer BioNTech</td>
<td></td>
<td>0.2 mL/10 ug</td>
<td>Orange</td>
<td>At least 8 weeks after last monovalent dose</td>
</tr>
<tr>
<td>2 doses monovalent Moderna</td>
<td>NA; previously received 1 bivalent vaccine dose</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>and 1 dose bivalent mRNA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 or more doses monovalent</td>
<td>Pfizer-BioNTech</td>
<td>1</td>
<td>0.2 mL/10 ug</td>
<td>Orange</td>
<td>At least 8 weeks after last monovalent dose</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 doses monovalent Pfizer-</td>
<td>NA; previously received 1 bivalent vaccine dose</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>BioNTech and 1 dose bivalent Pfizer-BioNTech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Age 5 years