COVID-19 surveillance and vaccine recommendations update

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[cdc.gov/coronavirus]

Weekly Trends in Reported COVID-19 Cases, United States

As of October 26, 2022: 97,329,787 reported cases

[Accessed October 31, 2022]

CDC COVID Data Tracker: [https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00)
Weekly Trends in COVID-19-Associated Hospitalization Rates by Age Group
— COVID-NET, March 2020 – October 22, 2022

Since April, hospitalization rates in older ages increased relative to other age groups.

Age-Adjusted Rates of COVID-19-Associated Hospitalization by Vaccination Status and Receipt of Booster Dose in Adults Ages ≥18 Years, January 2021–August 2022

In August 2022, unvaccinated adults ages ≥18 years had 5.2X higher COVID-19-associated hospitalization rates compared to those vaccinated who are up to date with COVID-19 vaccination.
Trends in Weighted Variant Proportion Estimates & Nowcast
United States, July 30–October 29, 2022

Over 97% of currently circulating variants represent BA.4 or BA.5 Omicron sub-lineages

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 ≥25 years who were previously recommended to receive a monovalent booster dose

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

§At the September 1, 2022 meeting, ACIP discussed bivalent mRNA COVID-19 vaccines for all individuals ages ≥25 years who were previously recommended to receive a monovalent booster dose

### Bivalent mRNA Boosters

#### Monovalent COVID-19 vaccines

- **Modernat COVID-19 vaccine**
  - 50µg of spike protein from ‘ancestral’ (‘original’) SARS-CoV-2

- **Pfizer-BioNTech COVID-19 vaccine**
  - 30µg of spike protein from ‘ancestral’ (‘original’) SARS-CoV-2

#### Updated (Bivalent) COVID-19 vaccines

- **Modernat COVID-19 vaccine**
  - 50µg of spike protein from ‘ancestral’ (‘original’) SARS-CoV-2
  - 25µg of spike protein from Omicron (BA.4/BA.5) SARS-CoV-2

- **Pfizer-BioNTech COVID-19 vaccine**
  - 30µg of spike protein from ‘ancestral’ (‘original’) SARS-CoV-2
  - 15µg of spike protein from Omicron (BA.4/BA.5) SARS-CoV-2

Bivalent vaccines have the same total antigen amount as monovalent vaccines.

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### 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.

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Booster Recommendations: Monovalent Booster in Limited Situations

- A **monovalent Novavax booster dose** (instead of a bivalent mRNA booster dose) may be used in limited situations in people **ages 18 years and older** who completed any FDA-approved or FDA-authorized monovalent primary series, **have not received a previous booster dose(s)** and are:
  - Unable to receive an mRNA vaccine (i.e., an mRNA is contraindicated or not available)
  - Unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated
COVID-19 Vaccination Schedule for People Who Are **NOT** Moderately or Severely Immunocompromised

### Pediatric Schedule: Ages 6 months–4 Years

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

- Primary
  - 4-8 weeks
  - Primary

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

- Primary
  - 3-8 weeks
  - Primary
  - At least 8 weeks
  - Primary
Ages 6–11 years
(Primary Series:
Moderna or
Pfizer-BioNTech)

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

Pediatric Schedule: Ages 5–11 Years

Pediatric Schedule: Ages 12-17 Years

*3-8 week interval for Novavax or Pfizer-BioNTech; 4-8 week interval for Moderna
**2022 National Adult and Influenza Immunization Summit – 11/3/22**

**Adult Schedule: Ages 18 Years and Older**

**Ages 18 years and older**
(Primary Series: Moderna, Novavax, or Pfizer-BioNTech)

- Primary
- 3-8 or 4-8 weeks*
- At least 2 months
- Pfizer or Moderna Bivalent Booster†

*Regardless of previous monovalent booster doses given

**Ages 18 years and older**
(Primary Series: Janssen)

- Primary
- At least 2 months
- Pfizer or Moderna Bivalent Booster†

*Regardless of previous monovalent booster doses given

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*3-8 week interval for Novavax and Pfizer-BioNTech; 4-8 week interval for Moderna
† A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations in people ages 18 years and older who are unable to receive an mRNA vaccine (i.e., contraindicated) or unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated

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**Adult Schedule: Ages 18 Years and Older**

**Ages 18 years and older**
(Primary Series: Moderna, Novavax, or Pfizer-BioNTech)

- Primary
- 3-8 or 4-8 weeks*
- At least 6 months
- Novavax Booster†

† If unable or unwilling to get a bivalent mRNA

- Only WITHOUT receipt of previous booster(s)

**Ages 18 years and older**
(Primary Series: Janssen)

- Primary
- At least 6 months
- Novavax Booster†

† If unable or unwilling to get a bivalent mRNA

- Only WITHOUT receipt of previous booster(s)

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*3-8 week interval for Novavax and Pfizer-BioNTech; 4-8 week interval for Moderna
† A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations in people ages 18 years and older who completed any FDA-approved or FDA-authorized monovalent primary series, have not received a previous booster dose(s), and are unable to receive an mRNA vaccine (i.e., contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise remain unvaccinated
COVID-19 Vaccination Schedule for People Who ARE Moderately or Severely Immunocompromised

Pediatric Schedule: Ages 6 months–4 Years (Moderately or Severely Immunocompromised)

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

- Primary
- 4 weeks
- Primary
- At least 4 weeks
- Primary

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

- Primary
- 3 weeks
- Primary
- At least 8 weeks
- Primary
Pediatric Schedule: Ages 5–11 Years (Moderately or Severely Immunocompromised)

Ages 5 years (Primary Series: Moderna or Pfizer-BioNTech)
- Primary
- 3 or 4 weeks*
- At least 4 weeks
- Primary
- At least 2 months
- ONLY Pfizer Bivalent Booster

Regardless of previous monovalent booster doses given

*A 3-week interval for Pfizer-BioNTech; 4-week interval for Moderna

Ages 6–11 years (Primary Series: Moderna or Pfizer-BioNTech)
- Primary
- 3 or 4 weeks*
- At least 4 weeks
- Primary
- At least 2 months
- Pfizer or Moderna Bivalent Booster

Regardless of previous monovalent booster doses given

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*
- At least 4 weeks
- Primary
- At least 2 months
- Pfizer or Moderna Bivalent Booster

Regardless of previous monovalent booster doses given

*A 3-week interval for Novavax or Pfizer-BioNTech; 4-week interval for Moderna

Ages 12–17 years (Primary Series: Novavax)
- Primary
- 3 weeks
- At least 2 months
- Primary
- Pfizer or Moderna Bivalent Booster

Regardless of previous monovalent booster doses given

*A 3-week interval for Novavax or Pfizer-BioNTech; 4-week interval for Moderna
**Adult Schedule: Ages 18 years and older (Moderately or Severely Immunocompromised)**

**Ages 18 years and older**
(Primary Series: Moderna or Pfizer-BioNTech)

1. **Primary**: 3 or 4 weeks*
2. **Primary**: At least 4 weeks
3. **Primary**: At least 2 months

**Pfizer or Moderna Bivalent Booster**

Regardless of previous monovalent booster doses given

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**Ages 18 years and older**
(Primary Series: Novavax)

1. **Primary**: 3 weeks
2. **Primary**: At least 2 months

**Pfizer or Moderna Bivalent Booster**

Regardless of previous monovalent booster doses given

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**Ages 18 years and older**
(Primary Series: Janssen)

1. **Primary**: At least 4 weeks
2. **Addl. mRNA dose**: At least 2 months

**Pfizer or Moderna Bivalent Booster**

Regardless of previous monovalent booster doses given

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*3-week interval for Novavax and Pfizer-BioNTech; 4-week interval for Moderna.
**COVID-19 Vaccines: Moderna**

<table>
<thead>
<tr>
<th>Product</th>
<th>Product for ages 6 months–5 years</th>
<th>Product for ages 6–11 years</th>
<th>Product for ages 6 years and older</th>
<th>Product for ages 12 years and older</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 (mRNA concentration)</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>
<tr>
<td>Injection volume volume</td>
<td>0.25 mL</td>
<td>0.5 mL</td>
<td>6–11 years: 0.25 mL 12 years+: 0.5 mL</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>Dilution required</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Beyond-Use Date</td>
<td>12 hours</td>
<td>12 hours</td>
<td>12 hours</td>
<td>12 hours</td>
</tr>
<tr>
<td>Storage</td>
<td>Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days</td>
<td>Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days</td>
<td>Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days</td>
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</tr>
</tbody>
</table>

**Moderna Labels**

**Monovalent label**
Primary series only
Ages 6–11 years

**Bivalent label**
Booster dose only
Ages 6 years and older

Despite label, do NOT use for booster doses.
### COVID-19 Vaccines: Pfizer-BioNTech

<table>
<thead>
<tr>
<th>Product</th>
<th>Product for ages 6 months–4 years</th>
<th>Product for ages 5–11 years (monovalent)</th>
<th>Product for ages 5–11 years (bivalent)</th>
<th>Product for ages 12 years and older (monovalent)</th>
<th>Product for ages 12 years and older (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/label border 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 (mRNA concentration)</td>
<td>3 mcg</td>
<td>10 mcg</td>
<td>10 mcg</td>
<td>30 mcg</td>
<td>30 mcg</td>
</tr>
<tr>
<td>Injection volume</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
<td>0.3 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>Yes—1.3 mL</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Beyond-Use Date</td>
<td>12 hours after dilution</td>
<td>12 hours after dilution</td>
<td>12 hours after dilution</td>
<td>12 hours after puncture</td>
<td>12 hours after puncture</td>
</tr>
<tr>
<td>Storage</td>
<td>Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks</td>
<td>Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks</td>
<td>Ultra-cold freezer until expiration; Refrigerator (2°C–8°C) up to 10 weeks</td>
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</tr>
</tbody>
</table>

### Pfizer-BioNTech Labels

**Monovalent label**
Primary series only
Ages 12 years and older

**Bivalent label**
Booster dose only
Ages 12 years and older
**Vaccine Administration Errors: Monovalent mRNA Vaccine Given As Booster Dose**

- The dose generally does not need to be repeated.
- However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference.
- The repeat dose should be administered at least 2 months after the monovalent booster dose.

**Vaccine Administration Errors: Pfizer-BioNTech Bivalent Vaccine Given As Primary Dose**

- Do not repeat the dose. The bivalent dose can be counted as a primary series dose.
- Continue with the recommended vaccination schedule (i.e., complete the primary series, then administer a bivalent booster dose at least 2 months after completion of the primary series)
Vaccine Administration Errors: Moderna Bivalent Vaccine Given As Primary Dose

- Repeat 1 monovalent dose immediately (no minimum interval) because this is a lower-than-authorized dose for the primary series.
  - However, some experts suggest delaying the repeat dose for 8 weeks after the invalid dose.
- Continue with the recommended vaccination schedule (i.e., complete the primary series, then administer a bivalent booster dose at least 2 months after completion of the primary series)

COVID-19 Vaccination Clinical and Professional Resources: Your One-Stop-Shop

- https://www.cdc.gov/vaccines/covid-19/index.html

Find vaccine-specific job aids
Read the most updated clinical guidance
Stay up to date with requirements
Find a variety of tools to help you educate vaccine recipients
Interim Clinical Considerations for Use of COVID-19 Vaccines


US COVID-19 Vaccine Product Information

- [https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html)
Example Product Page

- Tools and resources
  - Storage and handling summary
  - Storage labels
  - Beyond-use date labels
  - Temperature logs
  - Vaccine expiration tracker
  - Schedule
  - Preparation and administration summary
  - Prevacination checklist
  - Standing orders
  - And more!

Example: COVID-19 Vaccines Preparation Summaries

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
FDA Resources


For more information, contact CDC
1-800-CDC-INFO (232-4636)

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

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 assessed 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