U.S. COVID-19 vaccine uptake among ages ≥12 years, August 2021-January 2023

Source: IZ Data Lake
U.S. COVID-19 Vaccination Coverage (%) of Total Population by Age Group — April 13, 2023

<table>
<thead>
<tr>
<th>Coverage / Age (years)</th>
<th>&lt;2</th>
<th>2-4</th>
<th>5-11</th>
<th>12-17</th>
<th>18-24</th>
<th>24-49</th>
<th>50-64</th>
<th>&gt;65</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1-dose†</td>
<td>8.6</td>
<td>10.7</td>
<td>39.9</td>
<td>72.1</td>
<td>82.2</td>
<td>85.4</td>
<td>95.0</td>
<td>95.0</td>
</tr>
<tr>
<td>Completed primary series</td>
<td>4.5</td>
<td>5.9</td>
<td>32.8</td>
<td>61.7</td>
<td>66.7</td>
<td>72.1</td>
<td>83.8</td>
<td>94.3</td>
</tr>
<tr>
<td>Bivalent booster</td>
<td>0.5</td>
<td>0.5</td>
<td>4.6</td>
<td>7.6</td>
<td>7.2</td>
<td>11.8</td>
<td>21.4</td>
<td>42.4</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>91.4</td>
<td>89.3</td>
<td>60.1</td>
<td>28.1</td>
<td>17.8</td>
<td>14.6</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

†Note: Coverage is capped at 95%
Source: https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends Updated April 13, 2023
Trends in weighted variant proportion estimates & Nowcast
United States, November 6, 2022-April 15, 2023

Collection date, week ending

Estimated Number of Reported COVID-19 Cases by Variant
Variant Proportions Scaled by Positive Nucleic Acid Amplification Test (NAAT) Counts

Weekly population-based rates of COVID-19-associated hospitalizations by age group—COVID-NET, March 2020–April 2023

Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

Updates to COVID-19 vaccine policy

Steps toward simple recommendations:
- Single formulation for mRNA COVID-19 vaccines
- Single (possibly annual) dose for most individuals
- Flexibility for vulnerable populations

COVID-19 vaccines: Where we are now
COVID-19 vaccines: Where we are going

Goal: Simple recommendations
Updates to COVID-19 vaccine policy

**Steps toward simple recommendations:**
Single formulation for mRNA COVID-19 vaccines
Single (annual?) dose for most individuals
Flexibility for vulnerable populations
Single formulation for mRNA COVID-19 vaccines

- Many monovalent COVID-19 vaccine products have already expired, others will expire soon
- With recent update, FDA removed authorizations for monovalent mRNA COVID-19 vaccine products
- Harmonization across recommendations with bivalent mRNA COVID-19 vaccines was discussed at VRBPAC in January and at ACIP meeting in February
Bivalent COVID-19 vaccines are able to **induce an immune response** when given either as a primary series or a booster dose

- Immunogenicity data showed that a BA.1 bivalent vaccine given as a primary series induced antibody titers to BA.1 that were 25 times higher than the original monovalent vaccine
- Percentage of patients reporting solicited local or systemic events was similar to or less than percentages seen after original vaccine, however this may be a result of the larger percent of seropositive participants in the bivalent vaccine group

Limited data to directly compare COVID-19 outcomes after receipt of a monovalent or bivalent vaccine

- Most studies show **improvement** in neutralizing antibodies for Omicron variants with a bivalent vaccine
- Bivalent vaccines **expanded** the immune response and provided increased **diversity** in antibody response
- While unable to directly compare clinical outcomes for monovalent and bivalent vaccines in the U.S., a study in the UK found **~10% increase** in VE for COVID-19 infections
Number of mRNA COVID-19 vaccine products

Moderna: 5 products

Pfizer-BioNTech: 6 products

Previously:
11 TOTAL Products!

Moderna: 2 products

Pfizer-BioNTech: 3 products

Moving forward:
5 Products

Eliminates look-alike vials for Moderna and Pfizer-BioNTech
Single formulation for mRNA COVID-19 vaccines
Summary from February ACIP meeting

- Receiving **COVID-19 vaccines** continues to be important for prevention of COVID-19 severe disease, hospitalization, and death
- Many children and adolescents remain unvaccinated for COVID-19
- COVID-19 vaccine recommendations that are **simple to implement** may remove some barriers to uptake
- Harmonizing the formulation for mRNA COVID-19 vaccines could simplify the presentations, reduce administration errors, and allow continued access to vaccines
- ACIP was **supportive** of a transition of the mRNA COVID-19 vaccine primary series from monovalent (original) to bivalent (original plus Omicron BA.4/5)
Single formulation for mRNA COVID-19 vaccines
Updates from FDA authorizations

- FDA removed the authorizations for monovalent mRNA COVID-19 vaccines
  - BLAs are still in place for monovalent products:
    - Comirnaty for ages 12 years and older, with limited doses in circulation
    - Spikevax for ages 18 years and older, but all doses are currently expired
- Bivalent mRNA COVID-19 vaccines are now authorized for all indications
- No changes to current language in other COVID-19 vaccine authorizations (Novavax or Janssen COVID-19 vaccines)
Single formulation for mRNA COVID-19 vaccines
Implications for CDC recommendations

- Transition to bivalent COVID-19 vaccines could *simplify* the presentations, reduce administration errors, and allow continued access to vaccines with expiration of monovalent products

Bivalent mRNA COVID-19 vaccines would now be recommended for *all indications*
Updates to COVID-19 vaccine policy

Steps toward simple recommendations:
- Single formulation for mRNA COVID-19 vaccines
- Single (annual?) dose for most individuals
- Flexibility for vulnerable populations
Shifts in vaccine-induced, infection-induced, and hybrid immunity against SARS-CoV-2 among people aged ≥16 years — United States, Quarter 2 2021–Quarter 3 2022

Source: CDC (unpublished)
Shifts in vaccine-induced, infection-induced, and hybrid immunity against SARS-CoV-2 among people aged ≥16 years by age group — United States, Q2 2021–Q3 2022

Source: CDC (unpublished)
How frequently should people get a COVID-19 vaccine?

- Increases in COVID-19 cases (left) and hospitalizations (right) have occurred:
  - During the **winter months** and/or
  - Due to emergence of new **immune escape variants**

[CDCWeekly Trends in Number of COVID-19 Cases](https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00)

[CDCNew Admissions of Patients with Confirmed COVID-19](https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions)
Single (possibly annual) COVID-19 vaccine dose
Summary from February ACIP meeting

- For most older children, adolescents, and adults, future doses will be additional ‘boost’ after prior infection, prior vaccination, or both
- Time since last COVID-19 vaccine dose may both increase the incremental benefits of a COVID-19 vaccine, and decrease the risk of myocarditis
- Vaccine protection likely declines over time
- Winter months and immune escape variants have impacted COVID-19 epidemiology
- A simplified, annual recommendation could help reduce vaccine and message fatigue
- A plan for a **fall booster dose** could provide added protection, at a time when many would be ~1 year from last dose
  - Future epidemiology and SARS-CoV-2 virus evolution could help determine the need for continued annual boosters
FDA authorized a single age-appropriate mRNA COVID-19 vaccine dose for most individuals.

A single age-appropriate dose of a bivalent **Moderna COVID-19 vaccine** is authorized for individuals ages 6 years and older who are unvaccinated, or at least 2 months after receipt of any monovalent COVID-19 vaccine.

A single age-appropriate dose of a bivalent **Pfizer COVID-19 vaccine** is authorized for individuals ages 5 years and older who are unvaccinated, or at least 2 months after receipt of any monovalent COVID-19 vaccine.
Pediatric infection-induced and combined (vaccine- and infection-induced) Seroprevalence from U.S. commercial laboratories — March–December 2022

Source: [https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence](https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence) and unpublished data (CDC)
COVID-19 vaccine recommendations in children 5 years and younger

- **Young children** likely still need a ‘prime’ and ‘boost’ to optimize immunity
- Young children will continue to age into the vaccine recommendations at 6 months and could be SARS-CoV-2 naïve
- Additional data forthcoming to evaluate benefits of a multi-dose primary series in all children ages 5 years and younger, or if the recommendations could be simplified
  - Cost effectiveness analysis
  - Additional antibody data in young children

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Single (possibly annual) COVID-19 vaccine dose
Updates from FDA authorizations

- FDA authorized one, two, or three doses of a bivalent mRNA COVID-19 vaccine for children 6 months – 4 or 5 years
- Number of doses depend on **age**, as well as **number** and **type** of prior COVID-19 vaccine doses received
A COVID-19 vaccine framework for a single dose could be easy for COVID-19 vaccine providers to implement, and for the public to understand.

The current recommendations for a single dose may evolve over time, and could move to an annual recommendation.

A single bivalent dose would be recommended for everyone ages 6 years and older.

- For most people, this is not a change: if someone has not received a bivalent vaccine dose yet, they are recommended to receive one, regardless of their previous vaccine history.

Children 6 months through 5 years would receive at least two COVID-19 vaccine doses, including at least one bivalent COVID-19 vaccine.

- Table and detailed guidance to be published in Interim Clinical Considerations.
Updates to COVID-19 vaccine policy

**Steps toward simple recommendations:**
- Single formulation for mRNA COVID-19 vaccines
- Single (annual?) dose for most individuals
- Flexibility for vulnerable populations
Weekly population-based rates of COVID-19-associated hospitalizations by age group—COVID-NET, March 2020–April 2023

Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.
Rates of COVID-19 deaths by vaccination status and age, adults ≥65 years — 24 U.S. Jurisdictions, April 2022–January 2023

Ages 65–79 years

Ages ≥80 years

Additional updated COVID-19 vaccine doses
Survey data

- In a January 2023 survey of adults who had previously received a bivalent booster:
  - 54% said they were awaiting new guidelines for additional doses
  - 86% said getting another booster shot was important or a top priority

The survey was conducted January 17 - January 24, 2023, online and by telephone among a nationally representative sample of 1,234 U.S. adults

Accessed February 7, 2023
COVID-19 vaccines and older adults (adults ages ≥65 years)
Summary from February ACIP meeting

- Older adults have higher rates of hospitalization than younger adults
- Among older adults, vaccination rates with a bivalent COVID-19 vaccine dose remain low
  - It is important for older adults to be up to date on current recommendations, including receiving a bivalent booster
- ACIP discussed that data were insufficient to support a routine recommendation for older adults to receive a COVID-19 vaccine doses every 6 months, but acknowledged this population may continue to be more vulnerable to severe COVID-19 and likely needs flexibility with COVID-19 vaccine recommendations
Flexibility for vulnerable populations
Updates from FDA authorizations

- For adults ages ≥65 years, a single dose of a bivalent mRNA COVID-19 vaccine (either Moderna COVID-19 Vaccine or Pfizer-BioNTech COVID-19 vaccine) may be administered at least 4 months following the first dose of a bivalent COVID-19 vaccine
Flexibility for vulnerable populations
Implications for CDC recommendations

- The bivalent COVID-19 vaccine continues to provide protection against severe COVID-19 disease, and rates of hospitalization or death among older adults who have received a bivalent booster continue to be low.

- However, some older adults may benefit from an additional updated COVID-19 vaccine dose prior to possible future recommendations for updated vaccines this fall.

Adults ages 65 years and older may now choose to receive another updated COVID-19 vaccine dose.
COVID-19 vaccines and people who are immunocompromised
Summary from February ACIP meeting

- Immunocompromised adults can have less robust immune response to COVID-19 vaccines
- There are no currently authorized prophylactic monoclonal antibody products for populations at highest risk of COVID-19
- ACIP discussed that data were insufficient to support a routine recommendation for people who are immunocompromised to receive a COVID-19 vaccine doses every 6 months, but acknowledged this population may continue to be more vulnerable to severe COVID-19 and likely needs flexibility with COVID-19 vaccine recommendations
Flexibility for vulnerable populations
Updates from FDA authorizations

- For persons with moderate to severely immunocompromising conditions, a single dose of a bivalent mRNA COVID-19 vaccine may be administered at least 2 months following the first dose of a bivalent COVID-19 vaccine.

- Additional age-appropriate bivalent mRNA COVID-19 vaccine doses may be administered to immunocompromised persons at the discretion of the healthcare provider, taking into consideration the individual’s clinical circumstances.
Flexibility for vulnerable populations
Implications for CDC recommendations

- For people who are immunocompromised, additional doses have been recommended previously and current updates continue to allow additional protection to a vulnerable population.
- Updates also allow **flexibility** to adjust to individual’s specific circumstances, including timing of immunosuppression as well as the possible need for re-vaccination after particular events (e.g. stem cell transplant).
  - Additional guidance to be published in *Interim Clinical Considerations*.

People who are immunocompromised may now **choose to receive** another updated COVID-19 vaccine dose **and**

Have the **flexibility** to receive **additional doses** based on their clinical circumstances.
Updates to COVID-19 vaccine policy

Steps toward simple recommendations:
- Single formulation for mRNA COVID-19 vaccines
- Single (possibly annual) dose for most individuals
- Flexibility for vulnerable populations

Goal: Simple recommendations
Updates to COVID-19 vaccine policy

Steps toward simple recommendations:
- Single formulation for mRNA COVID-19 vaccines
- Single (possibly annual) dose for most individuals
- Flexibility for vulnerable populations

Future additional steps may be possible:
- Simplifications for all COVID-19 vaccines
- Possible updated vaccines this fall
- Continue to evaluate data-driven ways to simplify pediatric program
- Flexibility and simple guidance

Goal:
Simple recommendations
COVID-19 vaccines continue to be the most effective tool we have to prevent serious illness, hospitalization and death from COVID-19

Simple recommendations are easier to communicate, which may improve uptake

Anticipate that an updated fall vaccine could be available

Based on available data, anticipate benefits of COVID-19 vaccines given this fall
  - Updates to COVID-19 vaccine policy can also acknowledge possible future recommendations

For most people, the current doses needed remain unchanged: a single bivalent vaccine is recommended and there could be an updated vaccine/recommendation this fall
  - Flexibility for vulnerable populations
    - Young children continue to be recommended for multiple doses to prime/boost immune response, and will continue to review additional data
Work Group interpretation
Steps toward simple recommendations

- Continue to **review data** and **evaluate COVID-19 vaccine program** in context of evolving epidemiology
- Early COVID-19 vaccine recommendations made in light of a highly susceptible, immune naive population, with limited treatment options
- Increases in population-level immunity through both vaccine and infection, SARS-CoV-2 virus evolution, availability of anti-viral treatments, and review of COVID-19 epidemiology and hospitalization rates can lead to **evidence-based updates** in vaccine policy
- **Work is ongoing** to review additional data, continue efforts for simplification
- Work Group supportive of **simplified recommendations** as well as **flexibility** for vulnerable populations
Acknowledgments

- Monica Godfrey
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- Mary Chamberland
- Elisha Hall
- Valerie Morelli
- JoEllen Wolicki
- Heather Scobie
- Sierra Scarbrough
- Jefferson Jones
- Aron Hall
- Barbara Mahon
- Coronavirus and other Respiratory Viruses Division
- National Center for Immunization and Respiratory Diseases
Question for ACIP

- What are ACIP's thoughts on simplified recommendations as well as flexibility for vulnerable populations?
For more information, contact CDC
1-800-CDC-INFO (232-4636)

Thank you

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.