**COVID-19 Vaccines:**
Policy Updates, Future Directions, and Bivalent Vaccination Coverage

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NAIIS Meeting
May 9, 2023

cdc.gov/coronavirus

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**Trends in weighted variant proportion estimates & Nowcast**
United States, November 6, 2022-April 15, 2023

Collection date, week ending

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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

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**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
Single formulation for mRNA COVID-19 vaccines
Benefits and Harms: Summary from previous ACIP meetings

- 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

Modern: 5 products

- Moderna: 2 products
- Pfizer-BioNTech: 3 products

Previously: 11 TOTAL Products!

Moving forward: 5 Products

Eliminates look-alike vials for Moderna and Pfizer-BioNTech
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 are now recommended for all indications
Updates to COVID-19 vaccine policy

Steps toward simple recommendations:
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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)
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

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

- 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.
**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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<th>Coverage / Age (years)</th>
<th>&lt;2 years</th>
<th>2–4 years</th>
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<tr>
<td>At least 1-dose</td>
<td>8.6</td>
<td>10.7</td>
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<tr>
<td>Completed primary series</td>
<td>4.5</td>
<td>5.9</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>91.4</td>
<td>89.3</td>
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Source: [https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence](https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence) and unpublished data (CDC)
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

Single (possibly annual) COVID-19 vaccine dose
Implications for CDC recommendations

- 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** is now 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 receive **at least two** COVID-19 vaccine doses, including **at least one bivalent** COVID-19 vaccine
  - Table and detailed guidance 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.
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)

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
Overview of recommendations

Previous recommendations for people aged ≥6 years without immunocompromise

**People ages 6 through 11 years**
- Moderna or Pfizer-BioNTech
  - Primary 3-8 weeks (Pfizer) or 4-8 weeks (Moderna)
  - Primary 3-8 weeks (Pfizer) or 4-8 weeks (Moderna)
  - 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 3-8 weeks (Novavax, Pfizer) or 4-8 weeks (Moderna)
  - Bivalent mRNA booster

**People ages 18 years and older who previously received Janssen primary series dose**
- Primary
  - At least 2 months
  - Bivalent mRNA booster

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*People aged 6 months–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 primary series.*

*The Moderna, Novavax, and Pfizer-BioNTech primary series booster doses are administered at least 2 months after the last completed booster dose.*

*A bivalent mRNA booster dose may be used in healthcare workers in people aged 18 years and older who completed a primary series using a COVID-19 vaccine, have not received any previous booster dose, and are unable to receive a monovalent mRNA vaccine.*

*Janssen COVID-19 vaccine should only be used in certain limited situations. See: https://www.cdc.gov/vaccines/schedules/clinical-considerations/appendix-descriptions#appendix-e
New recommendations for people aged ≥6 years without immunocompromise who have not yet received a bivalent mRNA dose

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

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

*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
**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
Update to COVID-19 vaccine policy

**Steps toward simple recommendations:**
- Single formulation for mRNA COVID-19 vaccines
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**Goal:**
Simple recommendations
Updates to COVID-19 vaccine policy

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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

Updates to COVID-19 vaccine policy

Steps toward 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
Updates to COVID-19 vaccine policy
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

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 11<sup>th</sup>, 2023**

*Please visit [https://emergency.cdc.gov/coca/](https://emergency.cdc.gov/coca/) for complete details*
End of the Public Health Emergency on May 11, 2023 and the COVID-19 Vaccination Program

- **What will change**
  - Possible reduced submission of vaccine administration data from some jurisdictions which may limit completeness of administration data on a national level
  - Most jurisdictions have signed a COVID-19 vaccine Data Use Agreement extension through the end of 2023

End of the Public Health Emergency on May 11, 2023 and the COVID-19 Vaccination Program

- **What will not change**
  - CDC working with public and private partners to learn more about the short- and long-term health effects associated with COVID-19, who is affected, and why – and implementing vaccine recommendations to optimize protection
  - FDA’s EUAs for COVID-19 products (including vaccines)
  - All vaccines purchased by the U.S. government will continue to be distributed and available for free

Public Health Emergency ending ≠ Commercialization
Commercialization of COVID-19 Vaccines

- Commercialization of COVID-19 vaccines is the transition of vaccines previously purchased by the U.S. Government (USG), to established pathways of procurement, distribution, and payment by both public and private payers.

- Timeline: Likely in early Fall
  - Considerations include what will be authorized by FDA and recommended by CDC, and what will align with a strain change for potential variants.

- After commercialization, vaccines will remain free for most people through the Vaccines for Children Program, Children’s Health Insurance Program, most commercial insurance, Medicare, and Medicaid programs.

https://aspr.hhs.gov/COVID-19/Pages/FAQ-Commercialization.aspx

Thank you

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.
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.