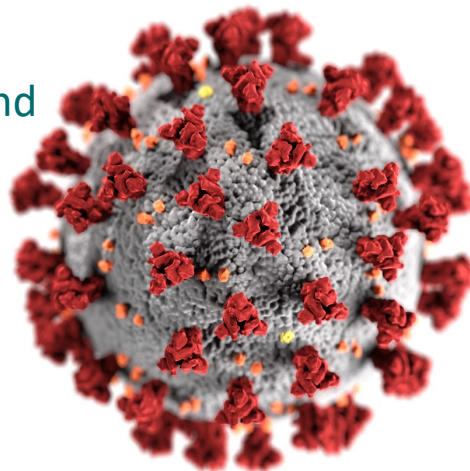


## COVID-19 Vaccines: Policy Updates, Future Directions, and Bivalent Vaccination Coverage

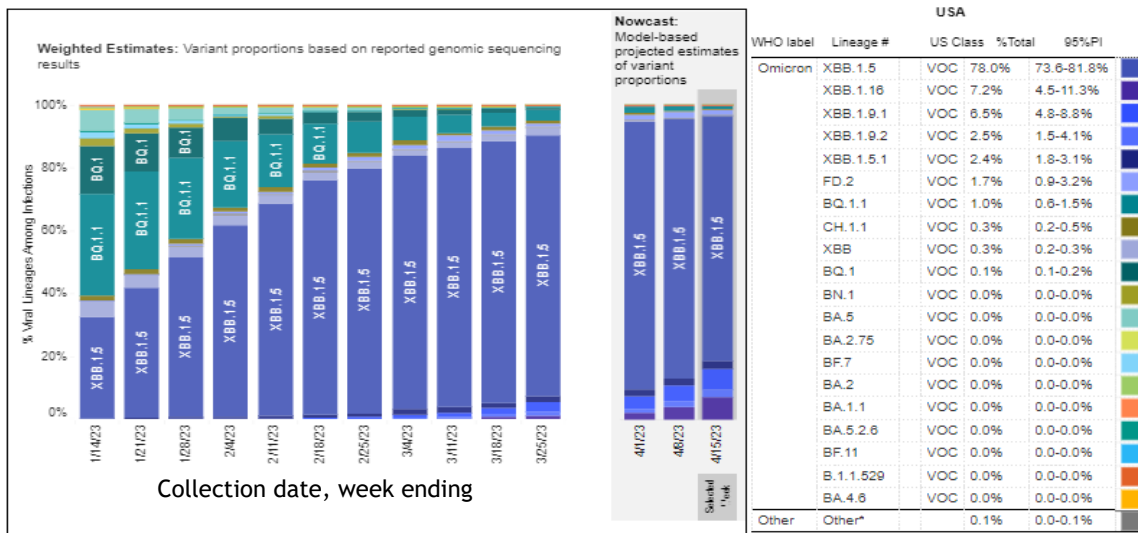


Sara Oliver, MD, MSPH  
NAIIS Meeting  
May 9, 2023



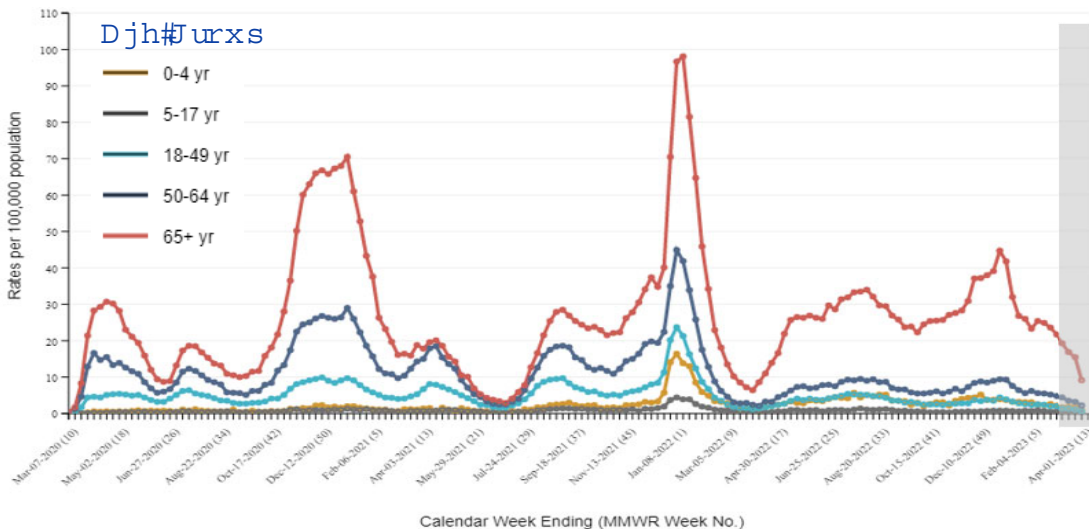
[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

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



PI=Prediction Interval, VOC=Variants of Concern, VBM=Variants Being Monitored. <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> Accessed April 18, 2023

### 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.  
<https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network> Accessed April 13, 2023

### 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

## 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

7

## Number of mRNA COVID-19 vaccine products

Moderna: 5 products



Moderna: 2 products



Pfizer-BioNTech: 6 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)

9

## 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**

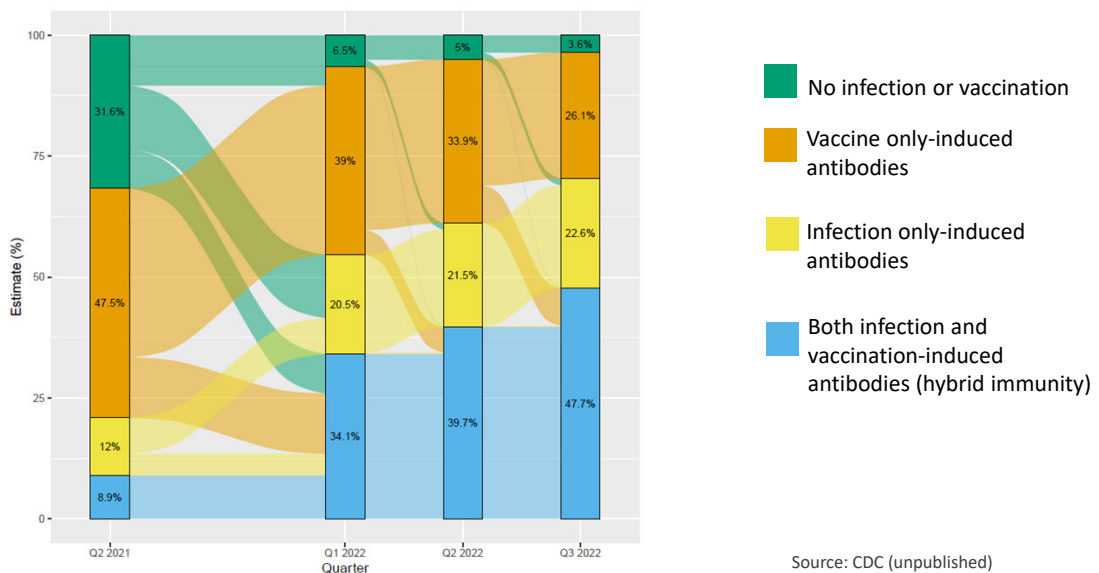
10

## 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



## 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

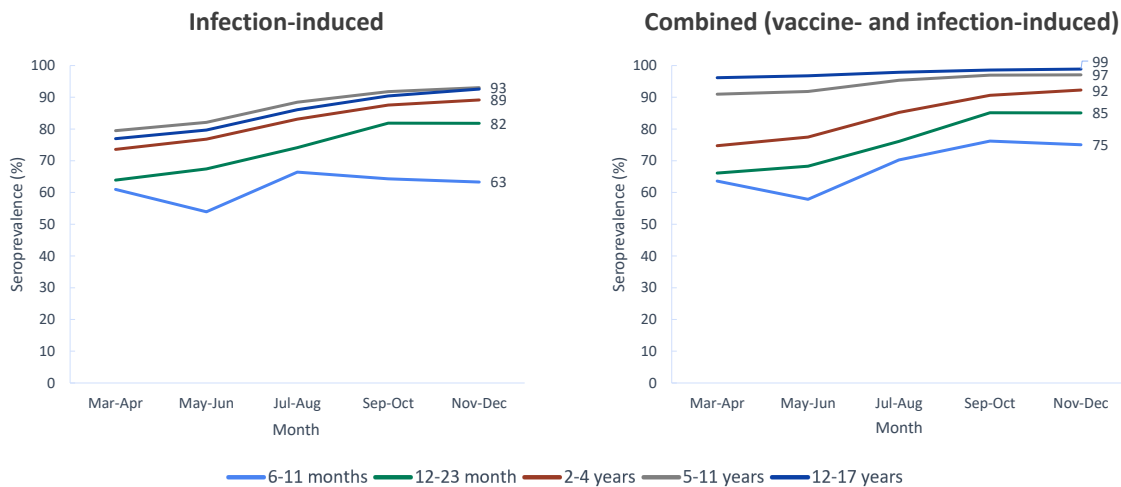


A **single age-appropriate dose** of a bivalent **Moderna COVID-19 vaccine** is authorized for individuals **ages 6 years and older** who are unvaccinated, or at least 2 months after receipt of any monovalent COVID-19 vaccine.



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.

### 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> 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

Coverage / Age (years)	<2 years	2–4 years
At least 1-dose	8.6	10.7
Completed primary series	4.5	5.9
Unvaccinated	91.4	89.3

## 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

17

## 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**

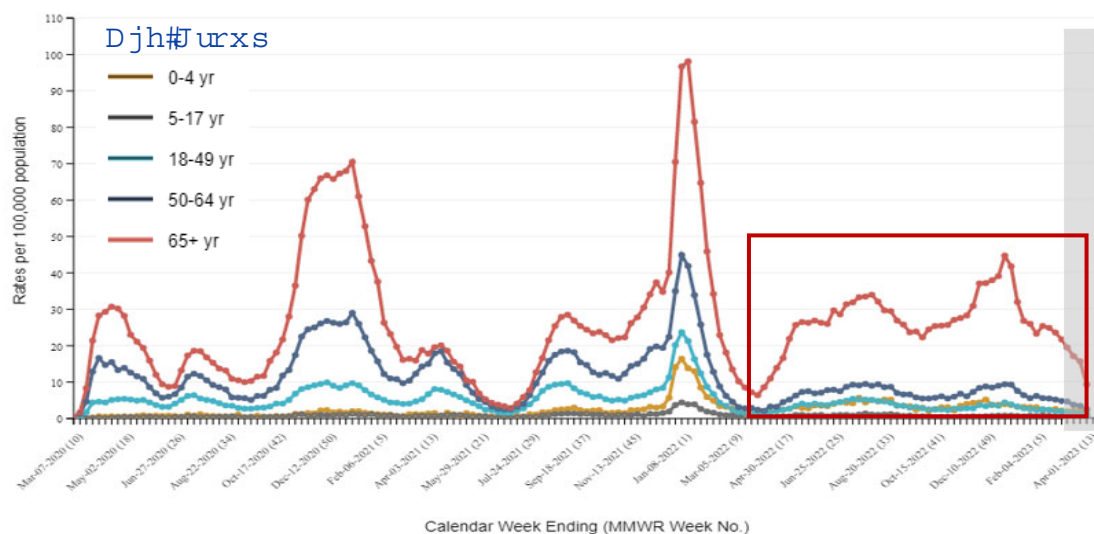
18

## 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.  
<https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network> Accessed April 13, 2023

## COVID-19 vaccines and older adults (adults ages $\geq 65$ 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  $\geq 65$  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

23

## 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

25

## 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)



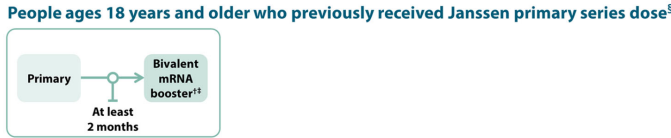
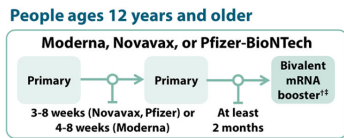
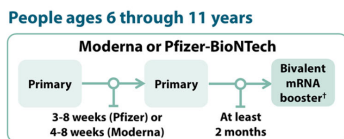
People who are immunocompromised may now **choose to receive** another updated COVID-19 vaccine dose -and-

Have the **flexibility** to receive **additional doses** based on their clinical circumstances

26

# Overview of recommendations

## Previous recommendations for people aged ≥6 years without immunocompromise



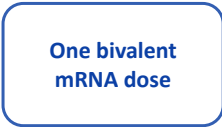
<sup>1</sup> People ages 6 months–4 years who previously completed a 3-dose monovalent Pfizer-BioNTech primary series are authorized to receive 1 bivalent Pfizer-BioNTech booster dose at least 2 months after completion of the monovalent primary series.

<sup>2</sup> 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.

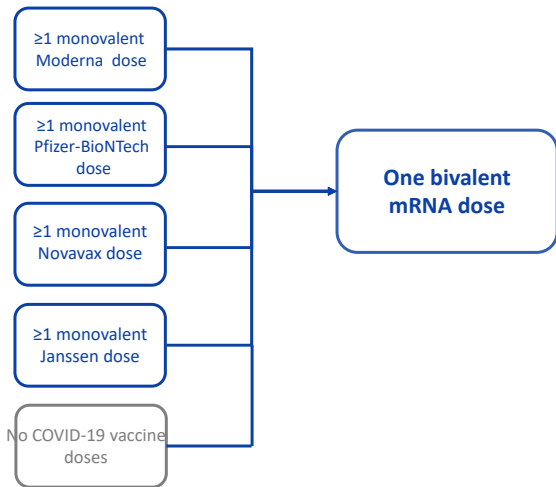
<sup>3</sup> A monovalent Novavax booster dose may be used in limited situations in people ages 18 years and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.

<sup>4</sup> 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 $\geq 6$ years without immunocompromise who have not yet received a bivalent mRNA dose



### New recommendations for people aged $\geq 6$ years without immunocompromise who have not yet received a bivalent mRNA dose, regardless of COVID-19 vaccination history



## New recommendations for aged $\geq 6$ years without immunocompromise who have already received a bivalent mRNA dose

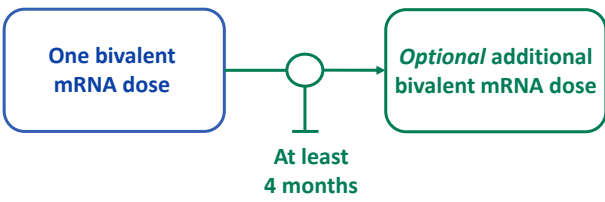


Vaccination is complete.  
No doses are indicated at this time.

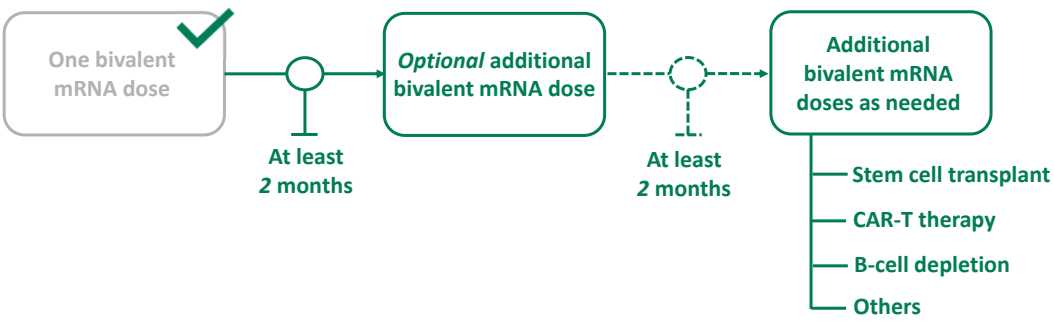
## Implications of the new recommendations

- 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  $\geq 65$  years who have not yet received a bivalent mRNA dose**



**New flexibility for people at higher risk of severe COVID-19:  
People aged  $\geq 6$  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

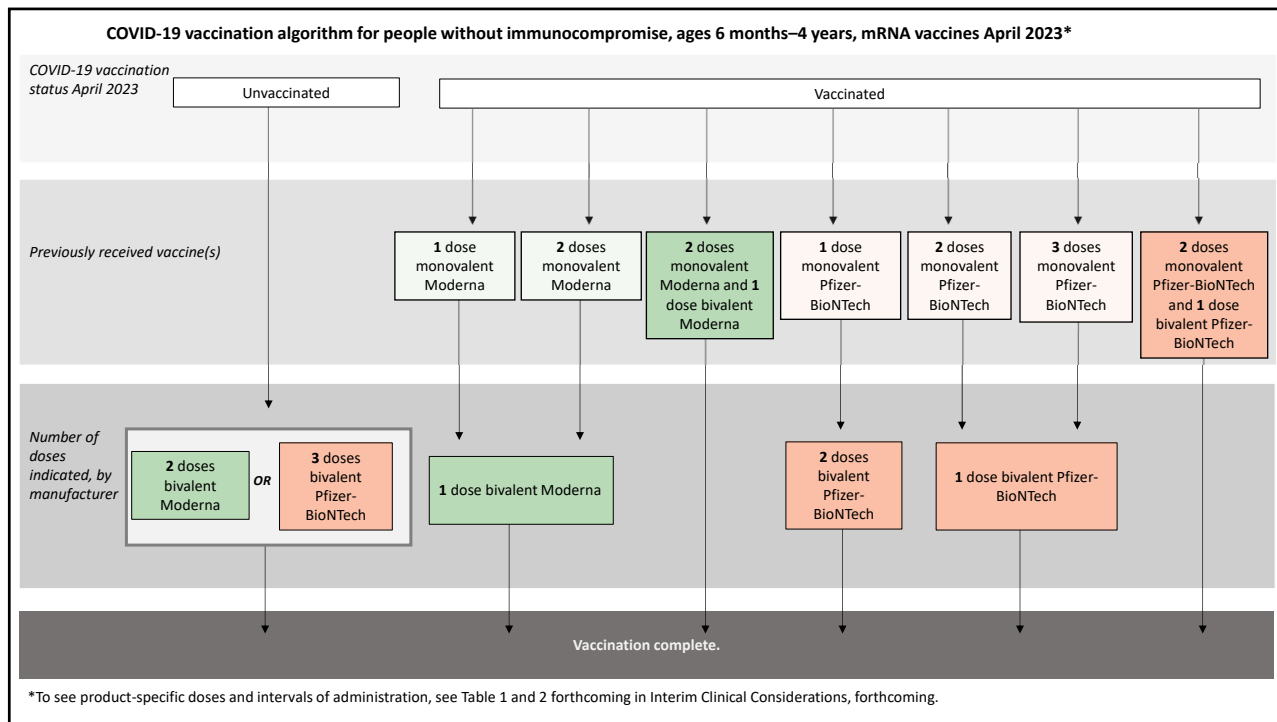
#### Pfizer:

- **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

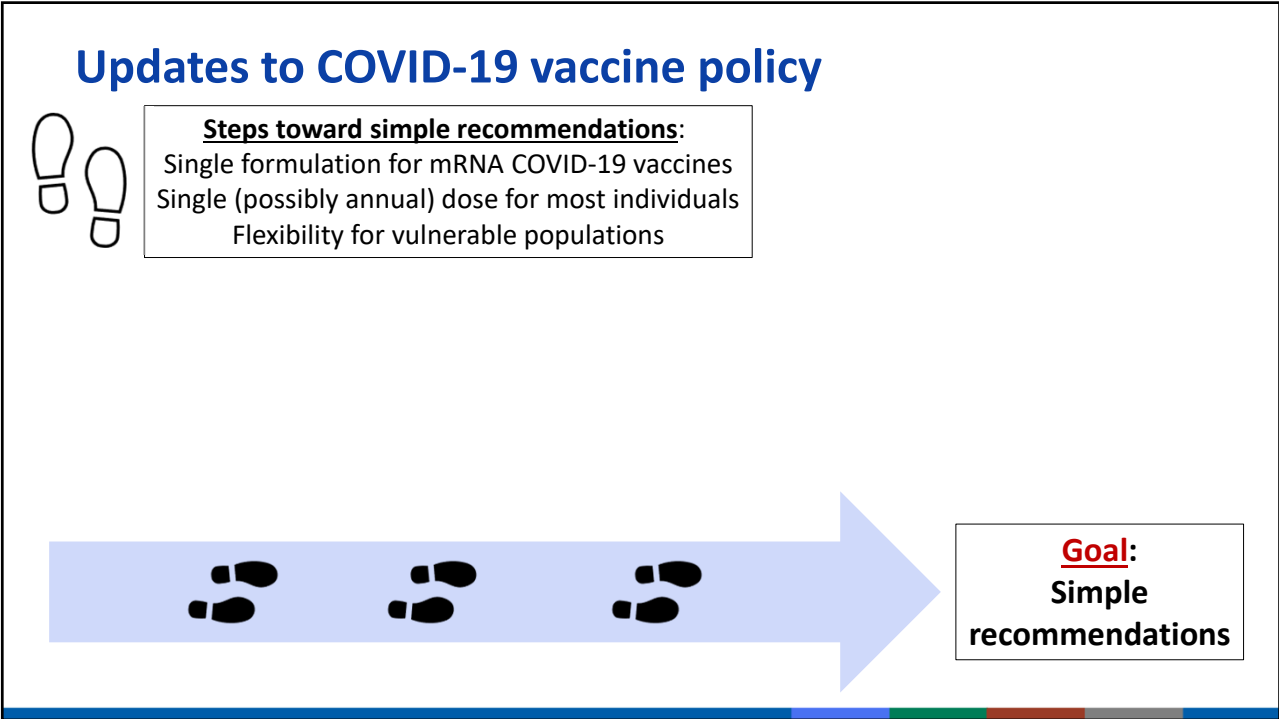
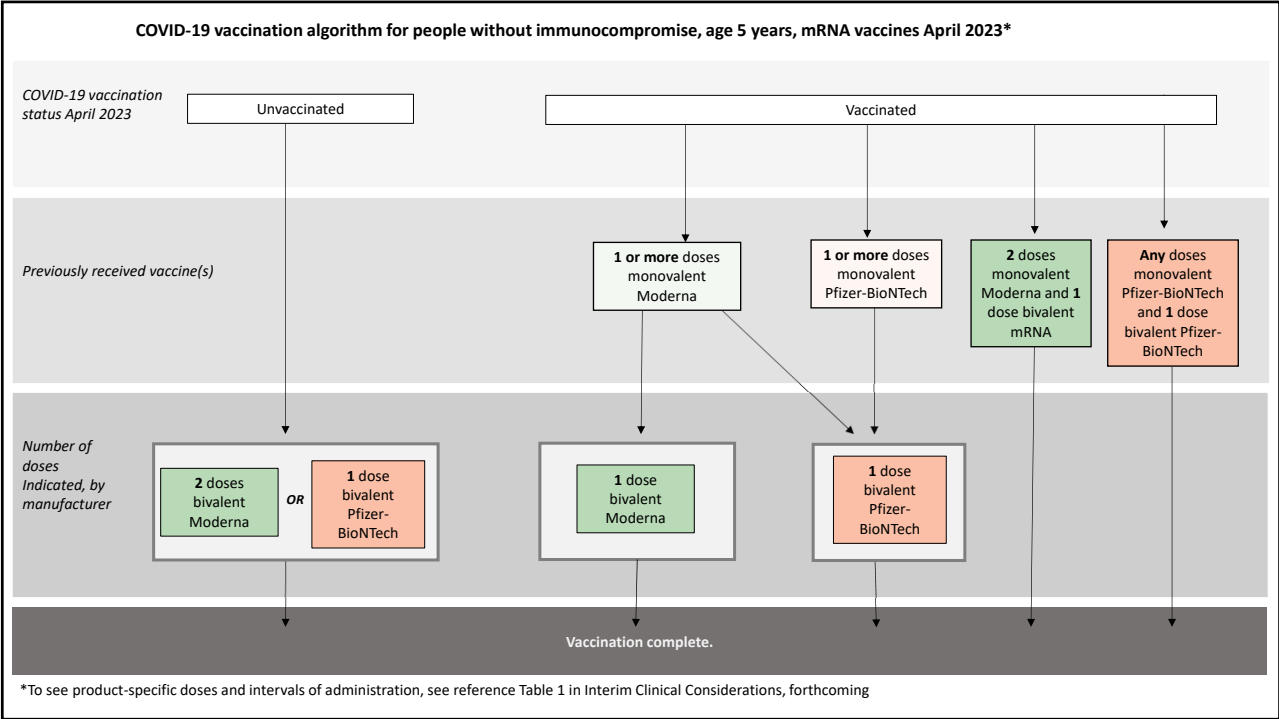
### Doses now recommended:

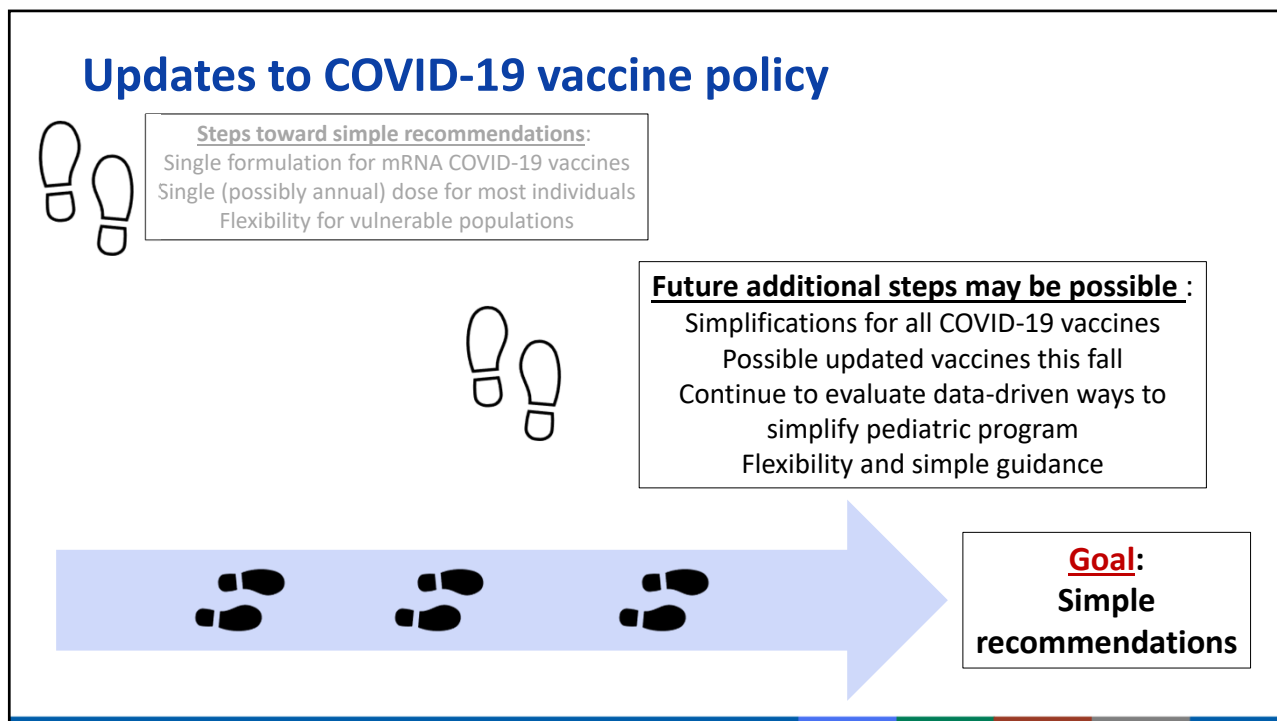
#### Customized so that Moderna recipients receive:

- At least 2 vaccine doses in total *including*
- At least **1 bivalent** dose

#### And Pfizer recipients receive:

- At least **1 bivalent** dose





## 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/> 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

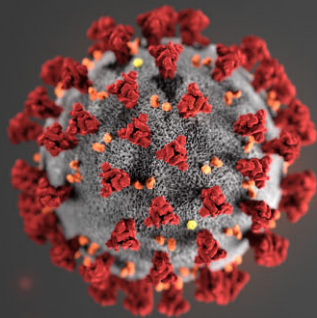
- CDC working with public and private partners to learn more about the short- and long-term health effects associated with COVID-19, who is affected, and why – and implementing vaccine recommendations to optimize protection
- FDA's EUAs for COVID-19 products (including vaccines)
- All vaccines purchased 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>



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

# 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.



## 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.