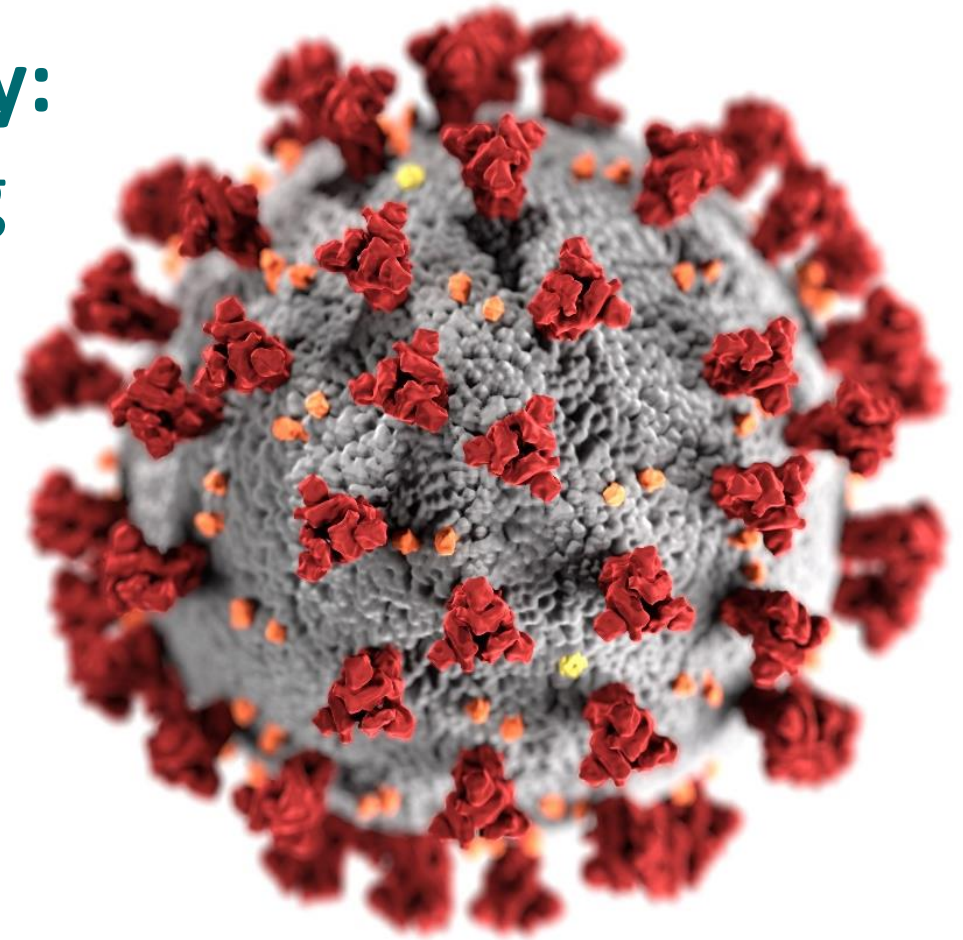


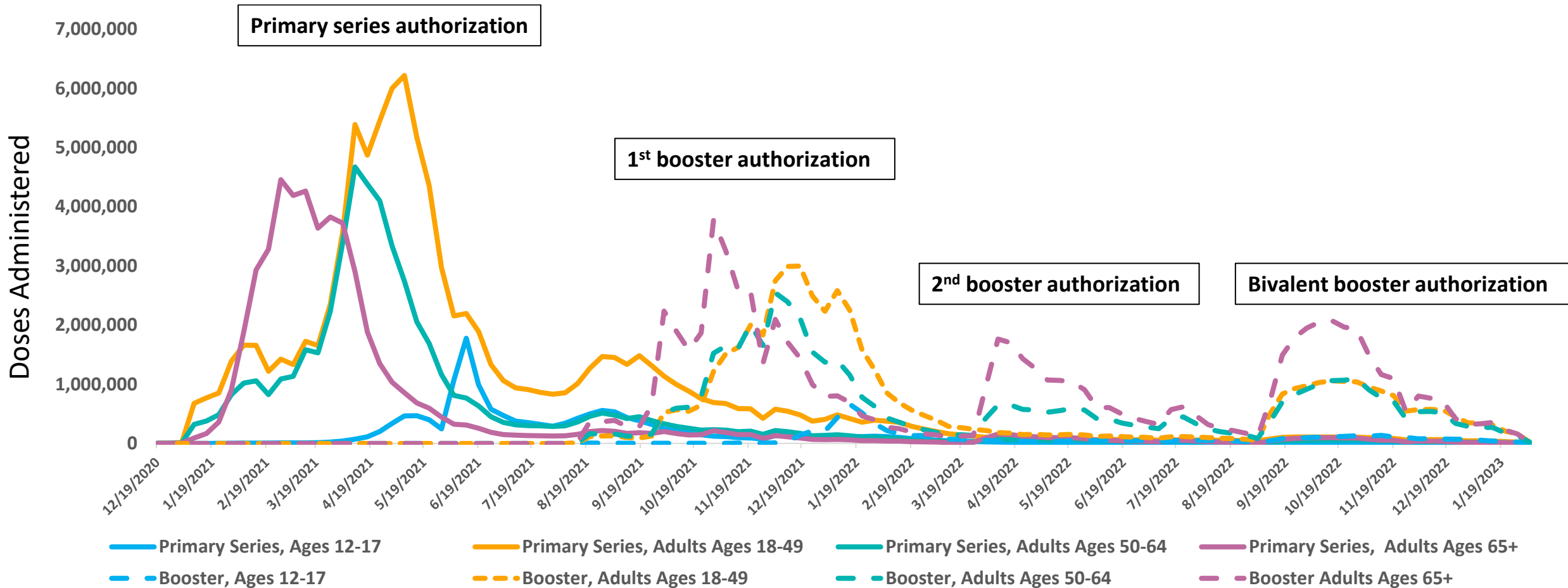
# Updates to COVID-19 vaccine policy: Considerations for Future Planning

Sara Oliver, MD, MSPH  
ACIP Meeting  
April 19, 2023



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

# U.S. COVID-19 vaccine uptake among ages $\geq 12$ years, August 2021-January 2023



# U.S. COVID-19 Vaccination Coverage (%) of Total Population by Age Group — April 13, 2023

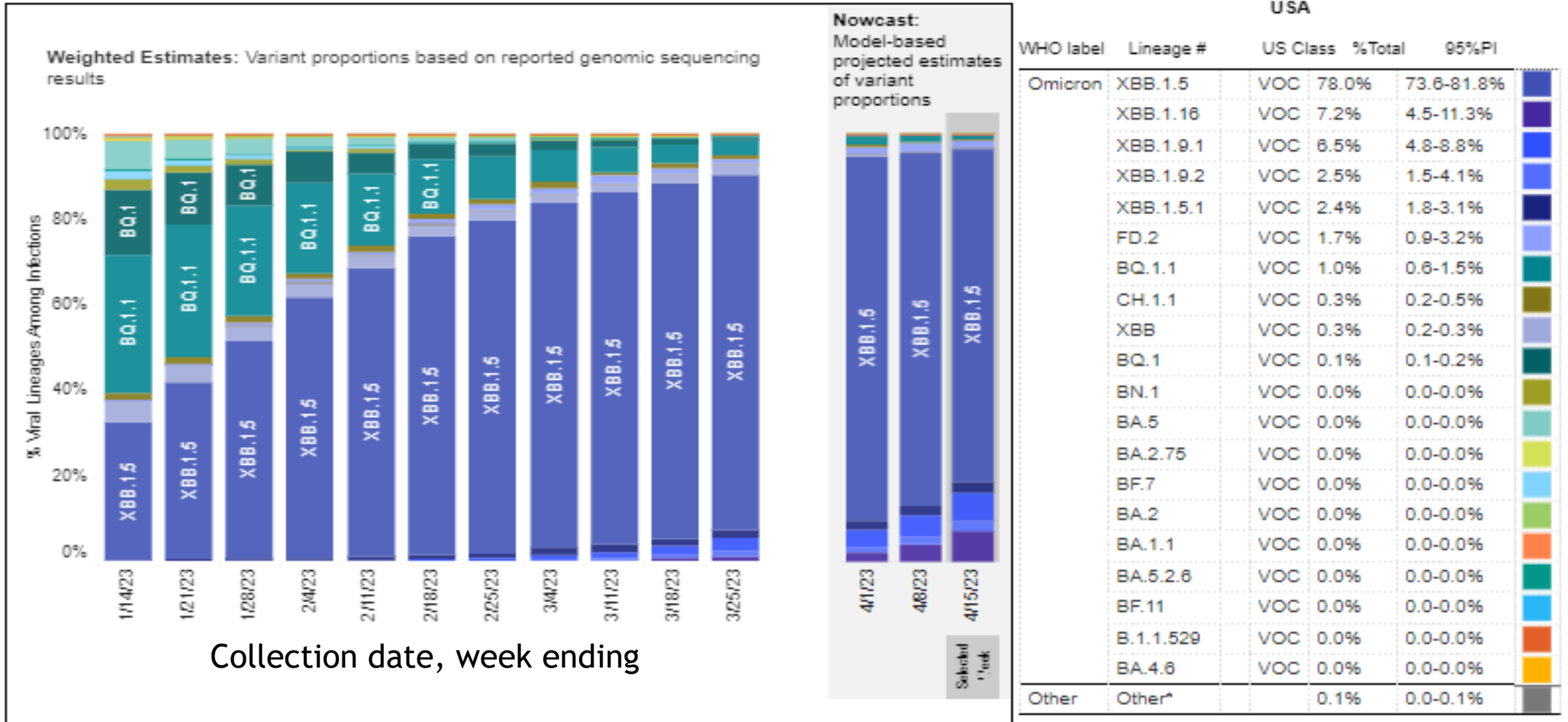
Coverage / Age (years)	<2	2-4	5-11	12-17	18-24	24-49	50-64	≥65
At least 1-dose <sup>†</sup>	8.6	10.7	39.9	72.1	82.2	85.4	95.0	95.0
Completed primary series	4.5	5.9	32.8	61.7	66.7	72.1	83.8	94.3
Bivalent booster	0.5	0.5	4.6	7.6	7.2	11.8	21.4	42.4
Unvaccinated	91.4	89.3	60.1	28.1	17.8	14.6	— <sup>†</sup>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

<sup>†</sup>Note: Coverage is capped at 95%

Source: <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends> Updated April 13, 2023

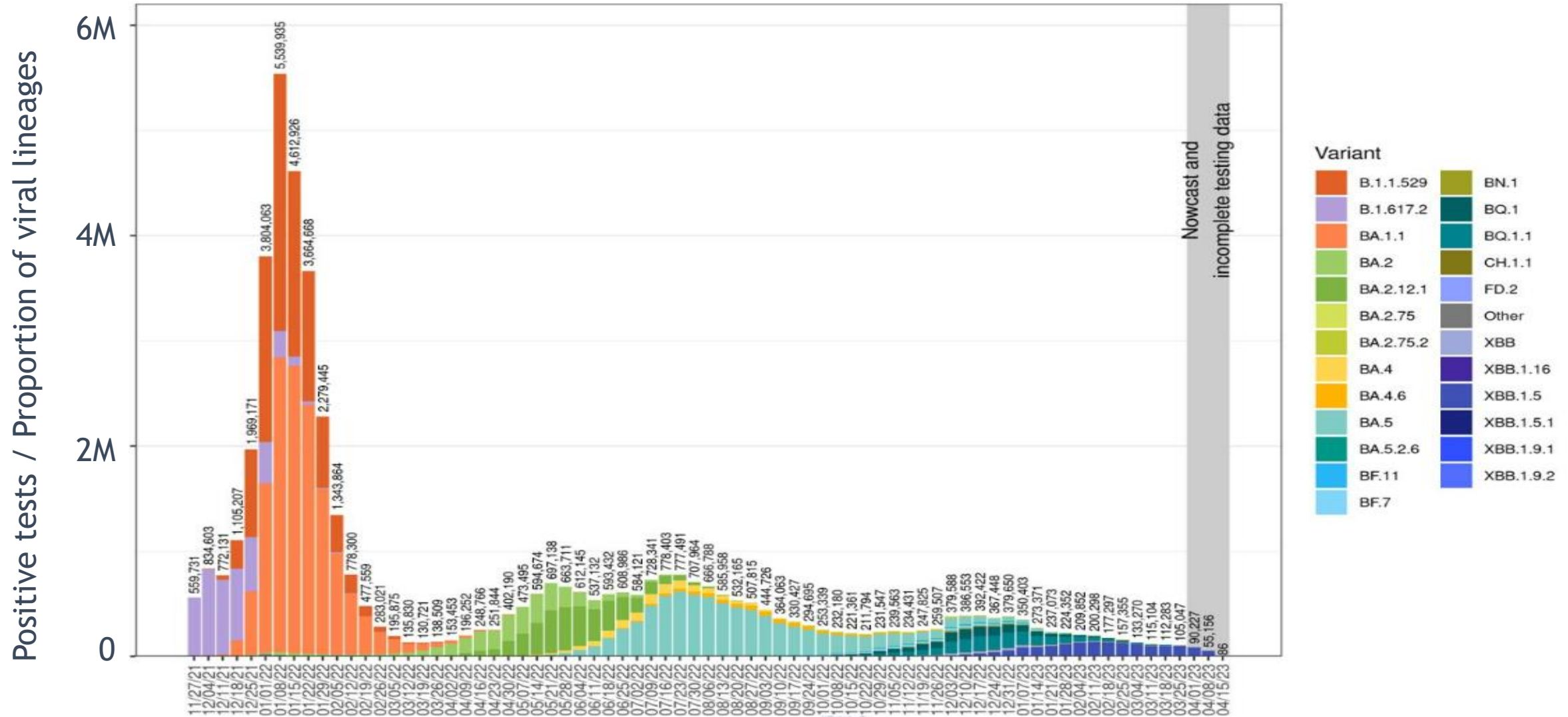
# Trends in weighted variant proportion estimates & Nowcast

## United States, November 6, 2022-April 15, 2023



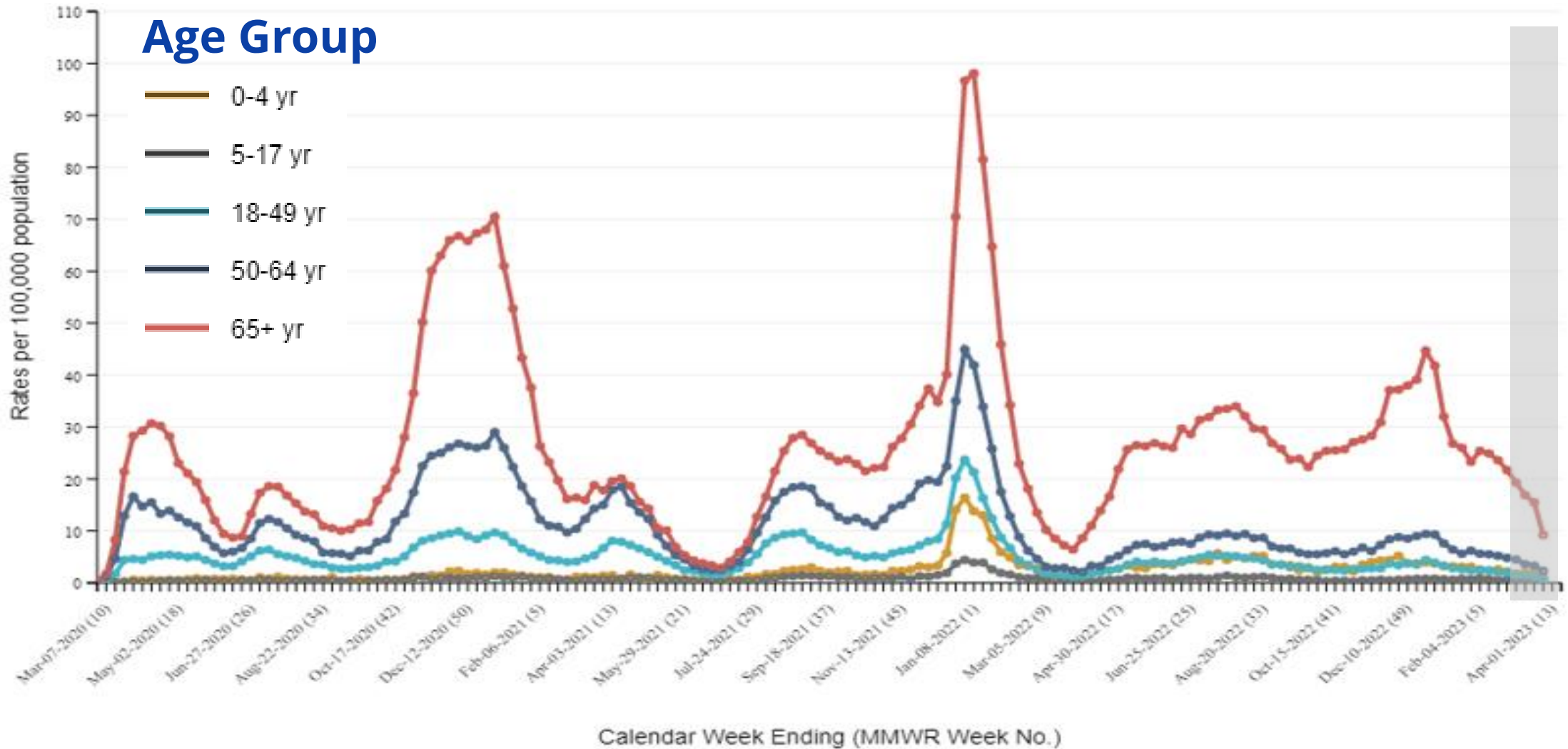
# Estimated Number of Reported COVID-19 Cases by Variant

## Variant Proportions Scaled by Positive Nucleic Acid Amplification Test (NAAT) Counts



CDC COVID-19 Lab Coordinating Unit Strain Surveillance and Emerging Variant Group. Data sources: <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> and [https://covid.cdc.gov/covid-data-tracker/#trends\\_newtestresultsreported\\_7daytestingpositive\\_00](https://covid.cdc.gov/covid-data-tracker/#trends_newtestresultsreported_7daytestingpositive_00)

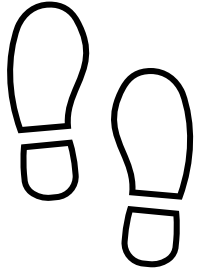
# Weekly population-based rates of COVID-19-associated hospitalizations by age group— COVID-NET, March 2020–April 2023



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:

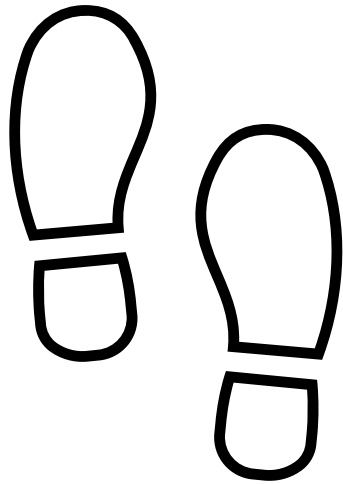
Single formulation for mRNA COVID-19 vaccines  
Single (possibly annual) dose for most individuals  
Flexibility for vulnerable populations

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

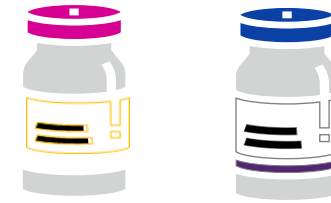
- Bivalent COVID-19 vaccines are able to **induce an immune response** when given either as a primary series or a booster dose
  - Immunogenicity data showed that a BA.1 bivalent vaccine given as a primary series induced antibody titers to BA.1 that were 25 times higher than the original monovalent vaccine
  - 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

# Number of mRNA COVID-19 vaccine products

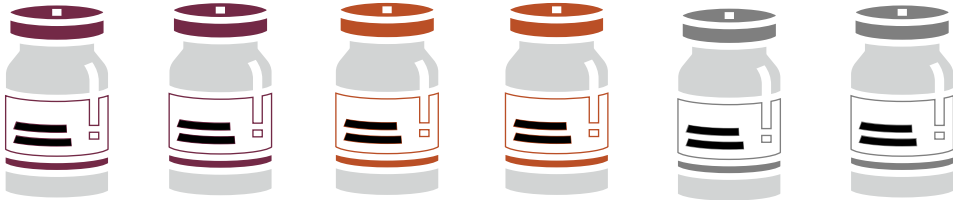
Moderna: 5 products



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

## 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

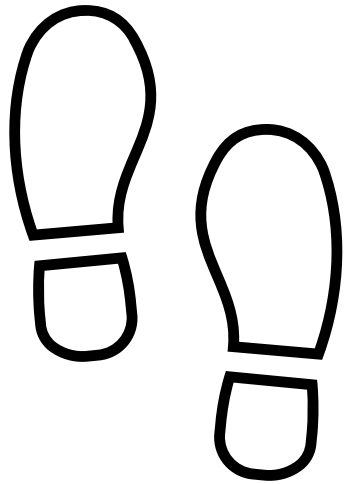
## Implications for CDC recommendations

- 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



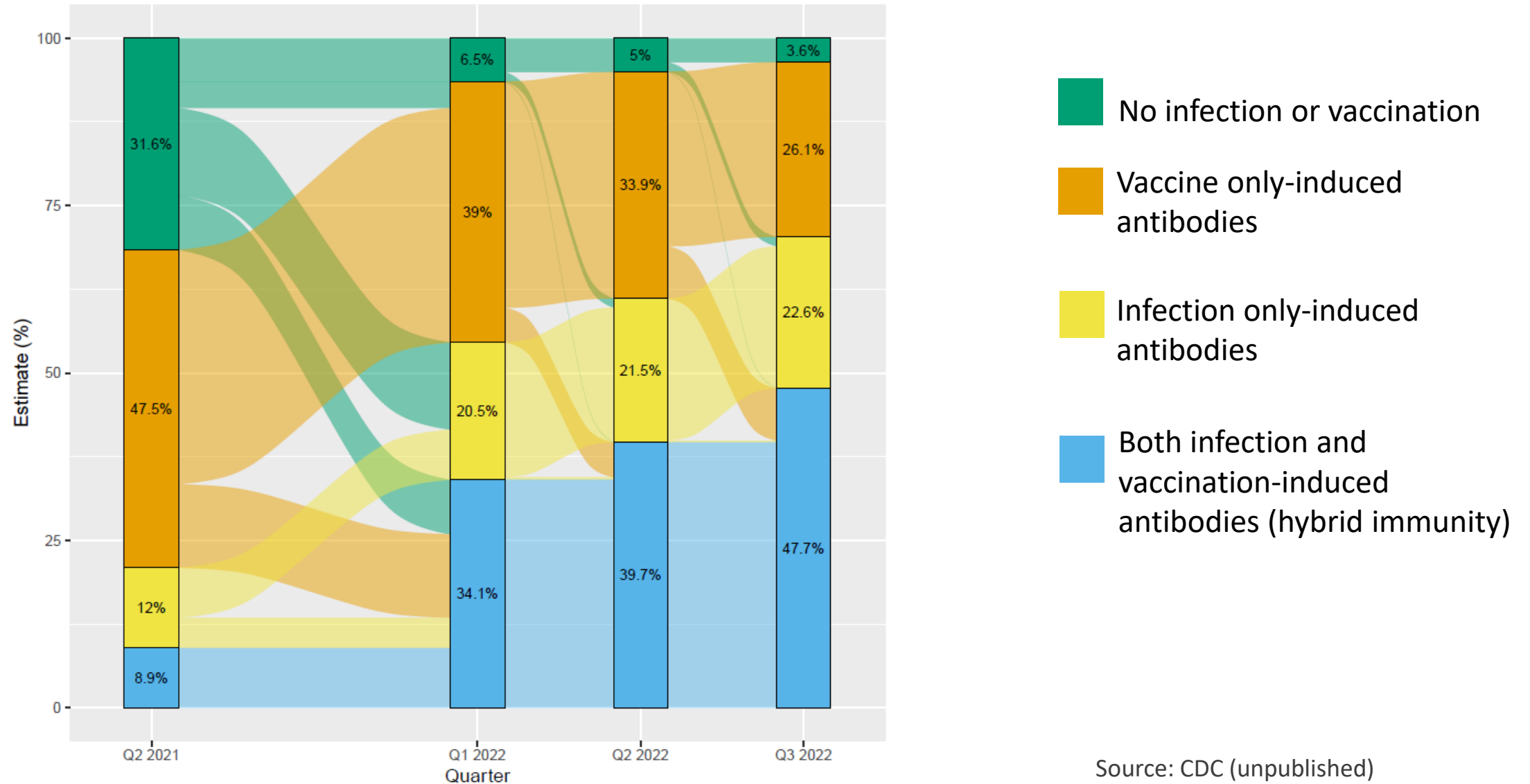
## Steps toward simple recommendations:

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Single (annual?) dose for most individuals

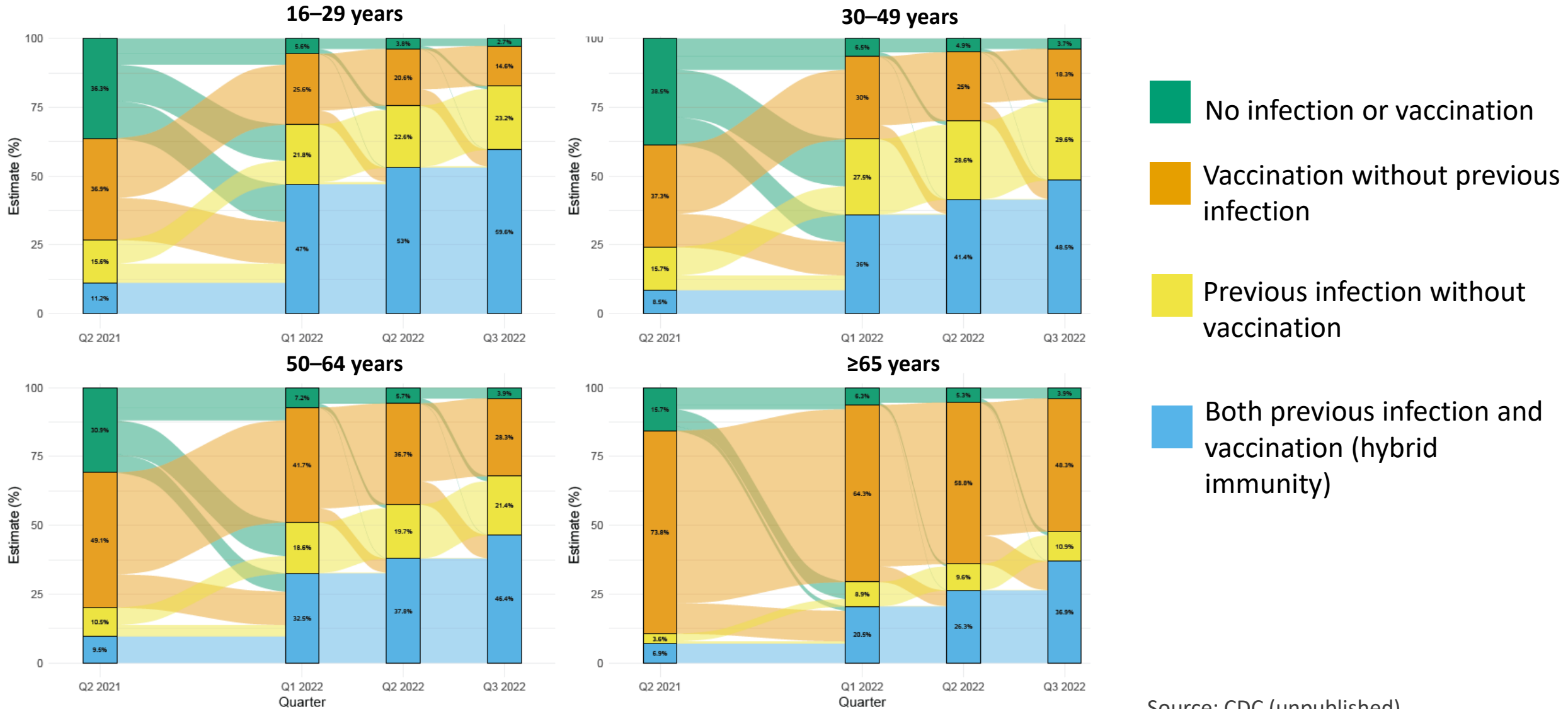
Flexibility for vulnerable populations

# Shifts in vaccine-induced, infection-induced, and hybrid immunity against SARS-CoV-2 among people aged $\geq 16$ years — United States, Quarter 2 2021– Quarter 3 2022





# 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



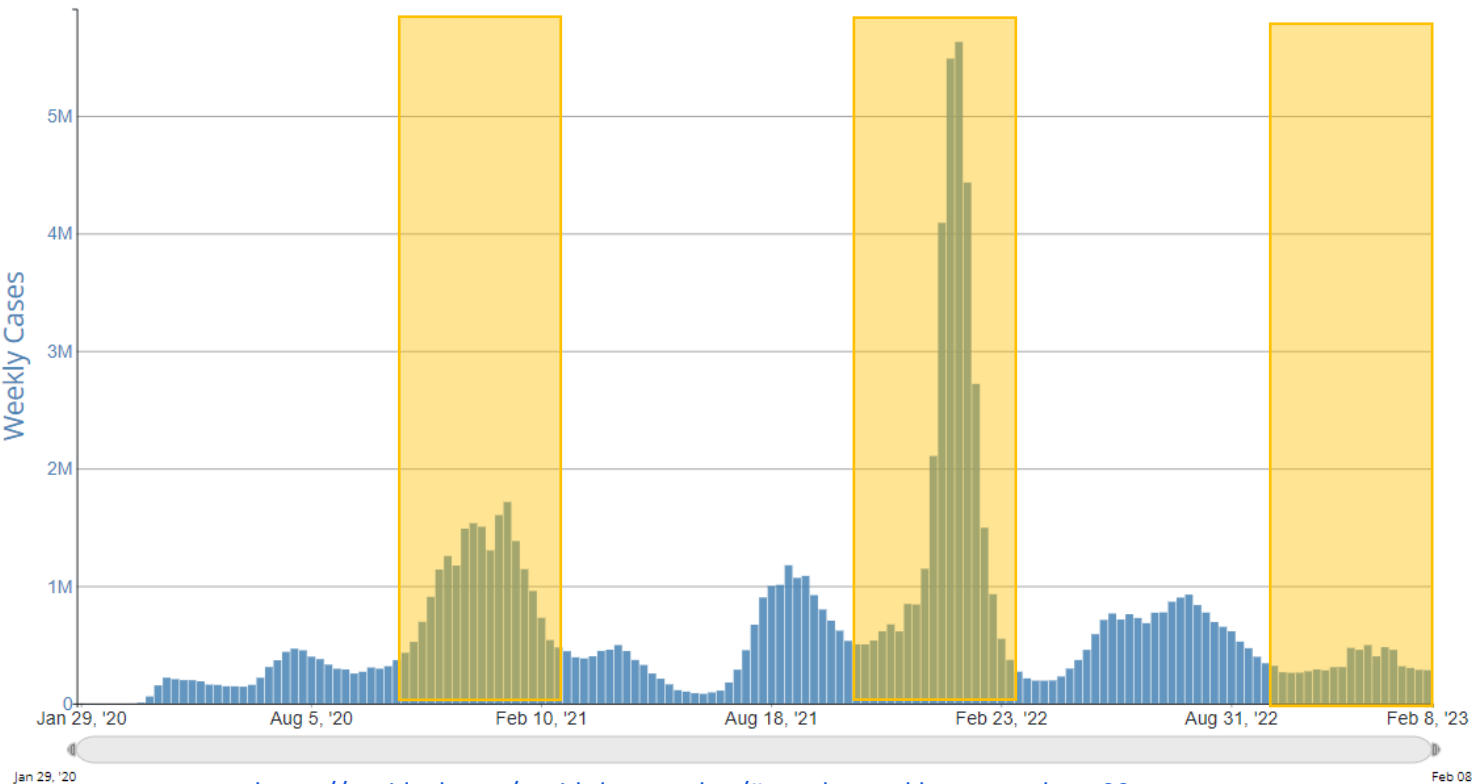
Source: CDC (unpublished)

# 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**

Cases from October 2021-February 2023 highlighted

Weekly Trends in Number of COVID-19 Cases in The United States Reported to CDC

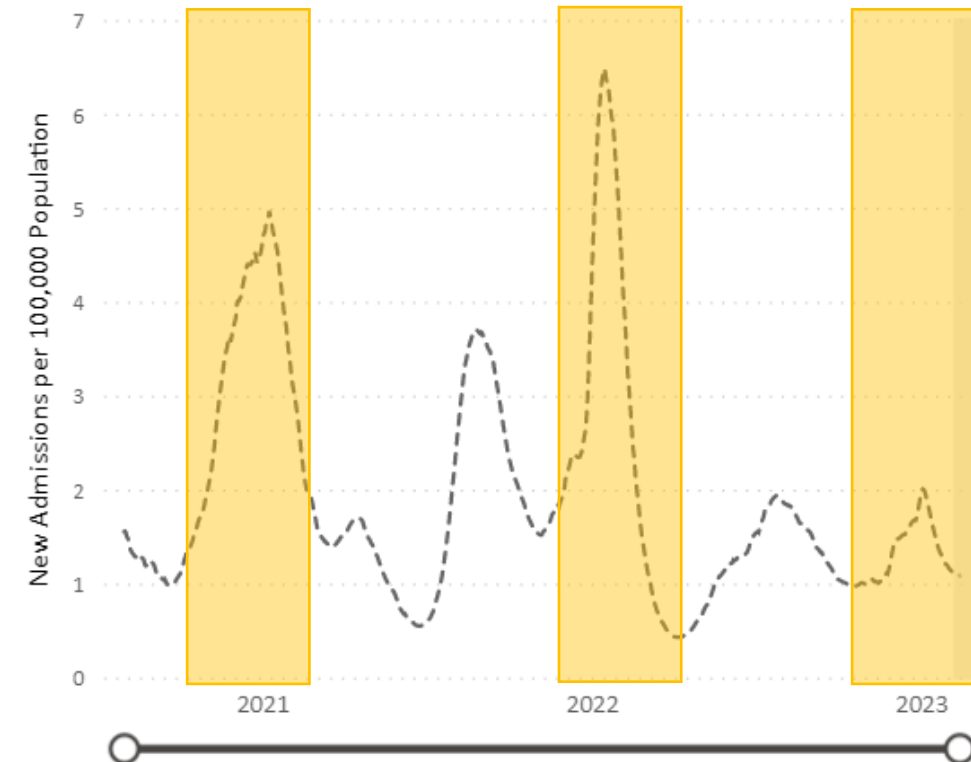


[https://covid.cdc.gov/covid-data-tracker/#trends\\_weeklycases\\_select\\_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00)

Admissions from October 2021 – February 2023 highlighted

New Admissions of Patients with Confirmed COVID-19, United States

Aug 01, 2020 - Feb 13, 2023



<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

# 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

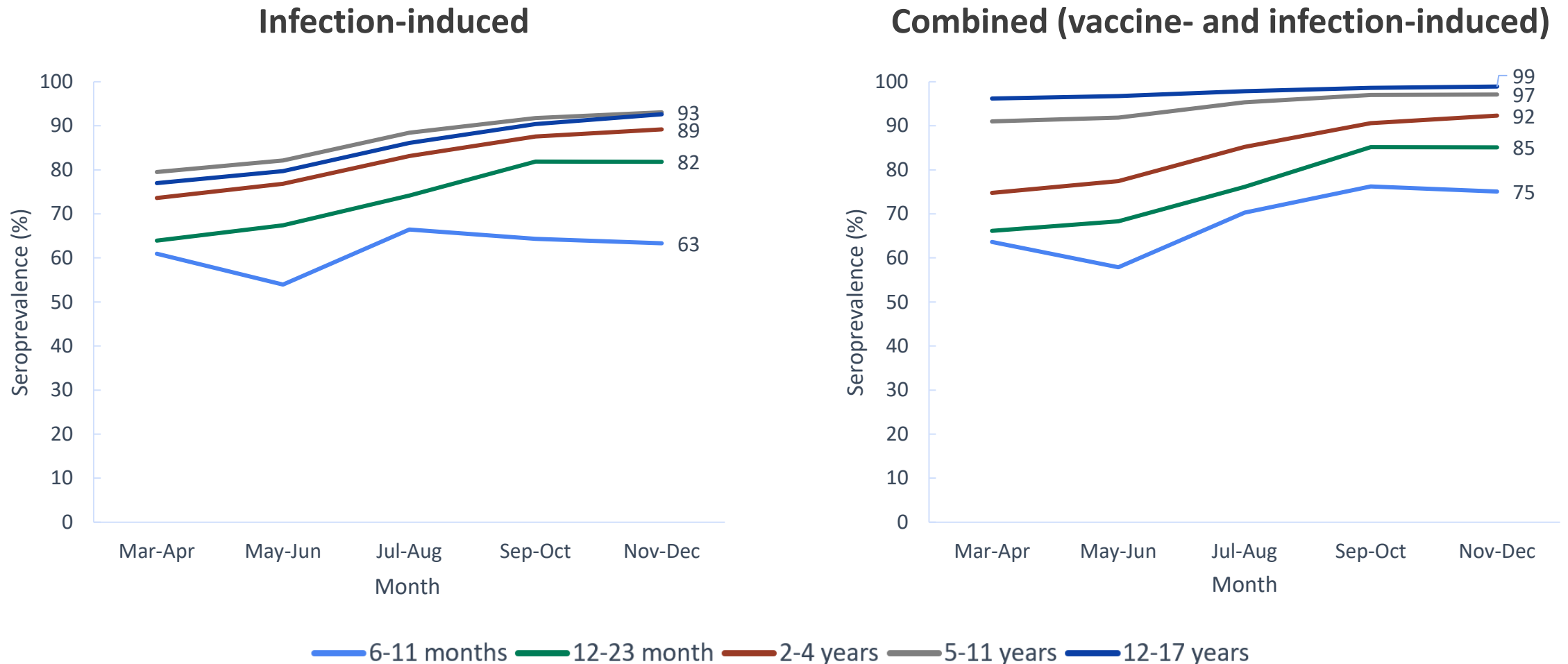


A **single age-appropriate dose** of a bivalent **Moderna COVID-19 vaccine** is authorized for individuals **ages 6 years and older** who are unvaccinated, or at least 2 months after receipt of any monovalent COVID-19 vaccine.



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



# 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


# 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** would be recommended for everyone ages 6 years and older

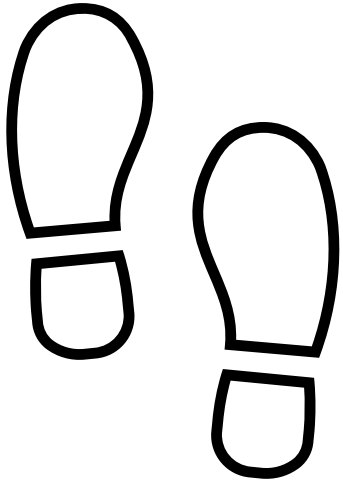
- For most people, this is not a change: if someone has not received a bivalent vaccine dose yet, they are recommended to receive one, regardless of their previous vaccine history

 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



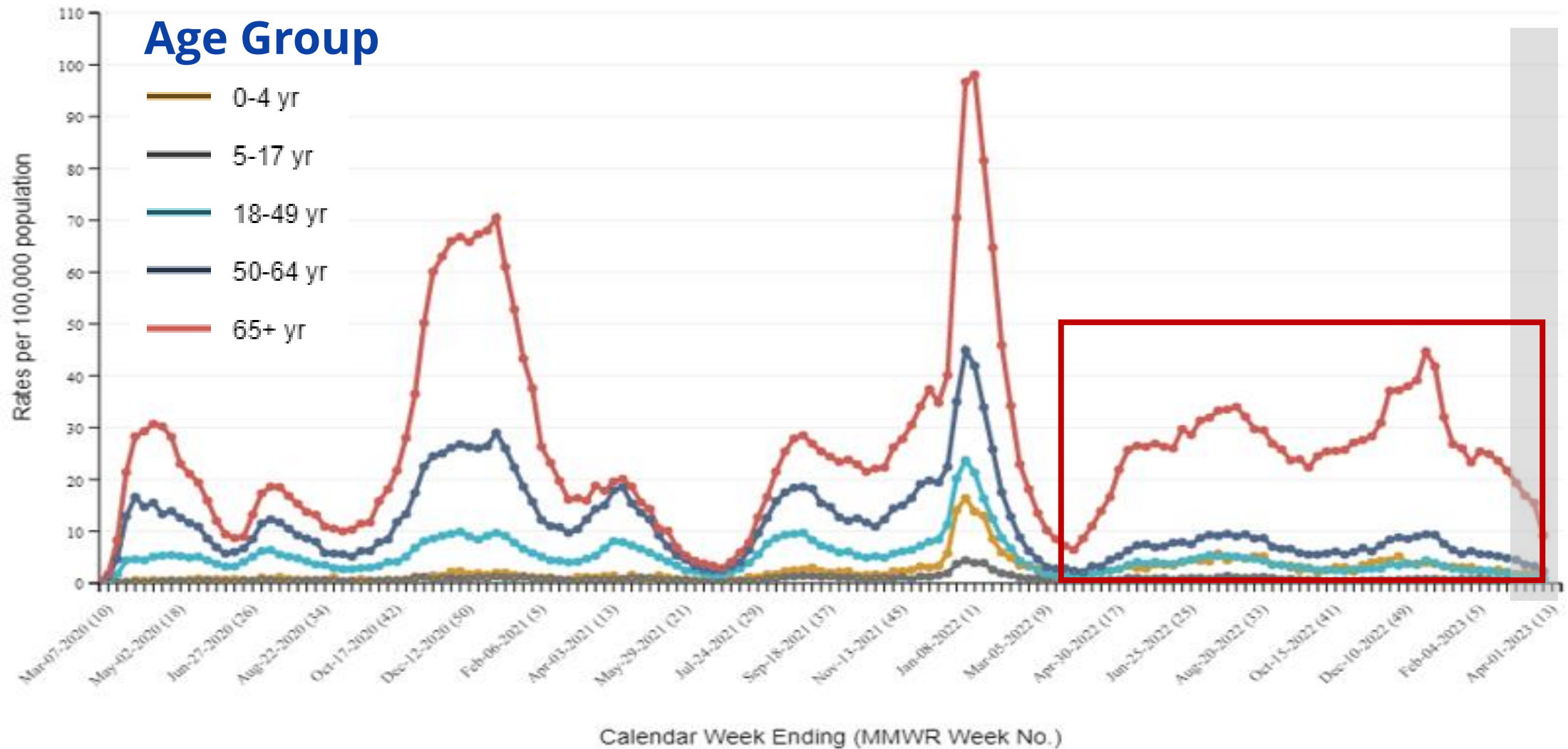
## Steps toward simple recommendations:

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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

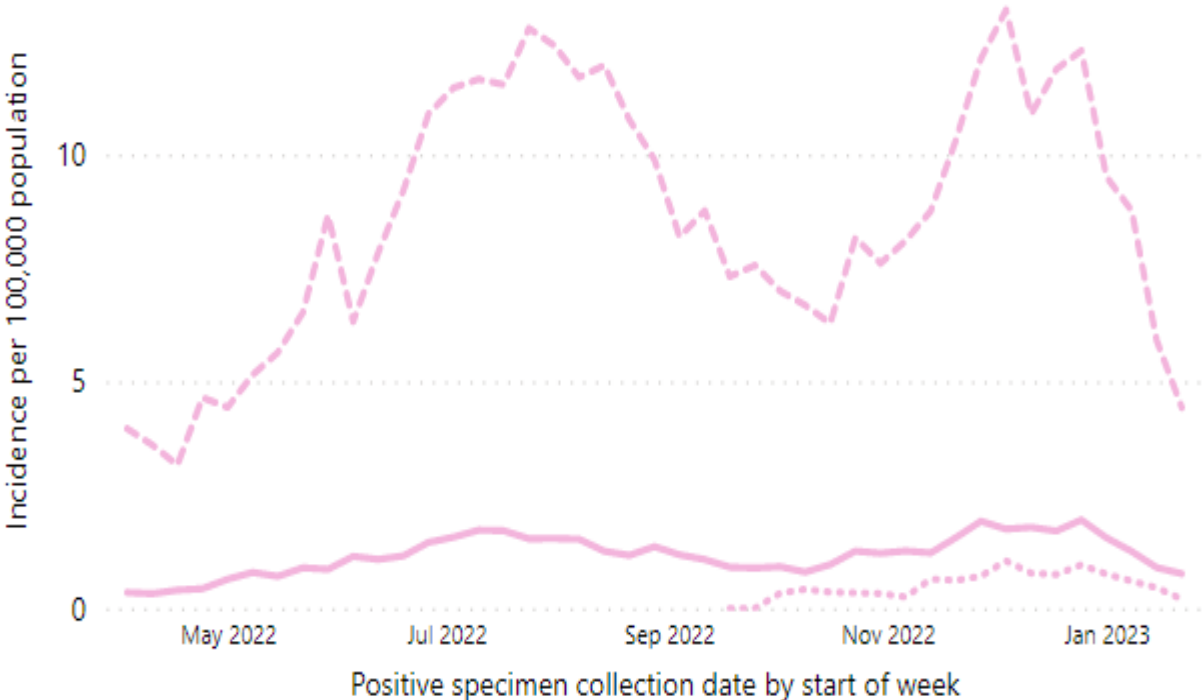


Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

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

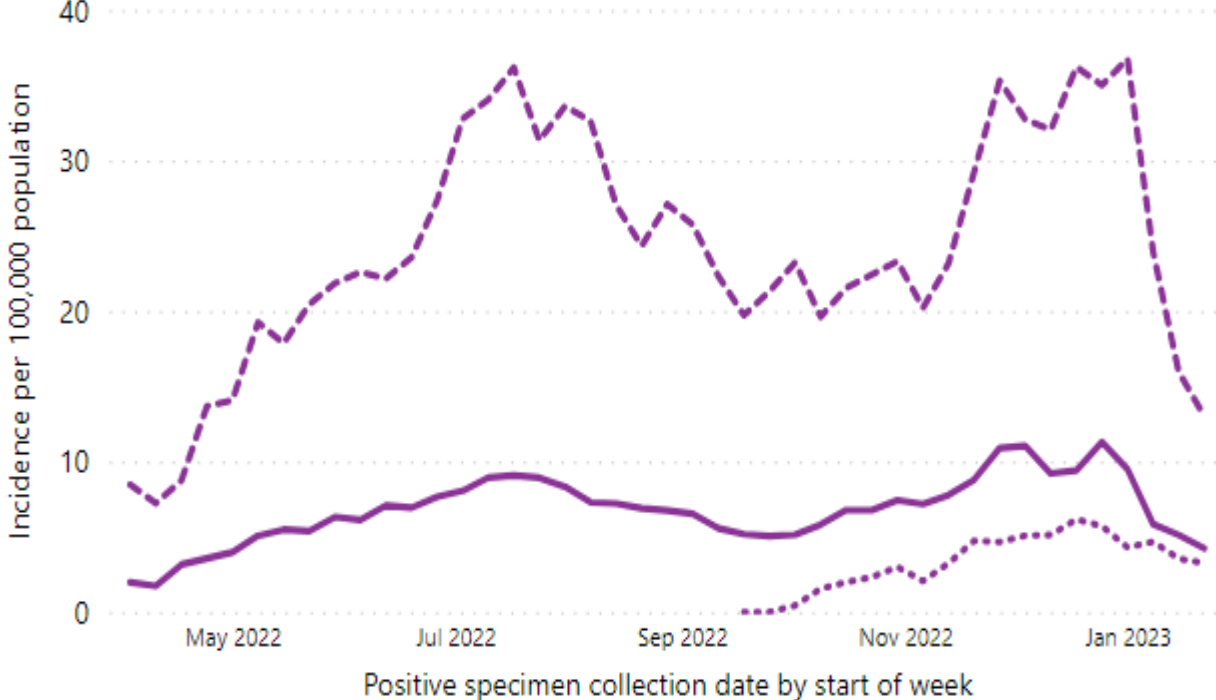
# Rates of COVID-19 deaths by vaccination status and age, adults ≥65 years — 24 U.S. Jurisdictions, April 2022–January 2023

## Ages 65–79 years



- Unvaccinated
- Vaccinated without updated booster
- ..... Vaccinated **with** updated booster

## Ages ≥80 years



- Unvaccinated
- Vaccinated without updated booster
- ..... Vaccinated **with** updated booster

# 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

# 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

# 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

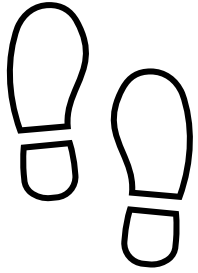
- For people who are immunocompromised, additional doses have been recommended previously and current updates continue to allow additional protection to a vulnerable population
- Updates also allow **flexibility** to adjust to individual's specific circumstances, including timing of immunosuppression 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

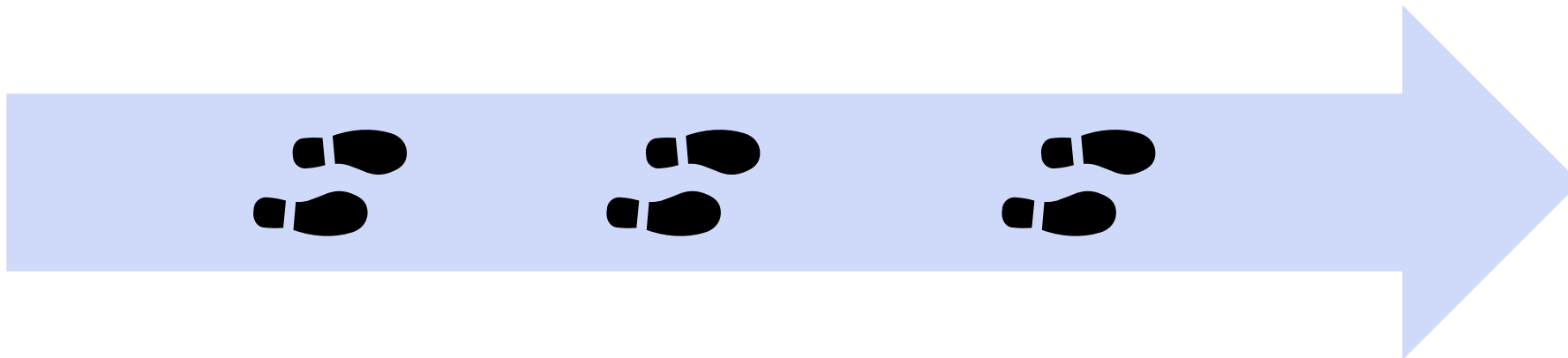


# Updates to COVID-19 vaccine policy



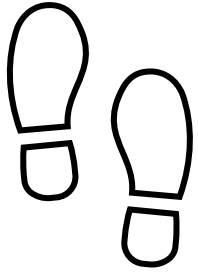
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Single formulation for mRNA COVID-19 vaccines  
Single (possibly annual) dose for most individuals  
Flexibility for vulnerable populations



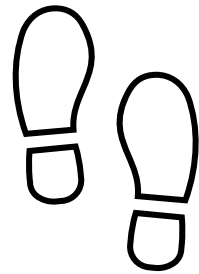
**Goal:**  
**Simple  
recommendations**

# Updates to COVID-19 vaccine policy



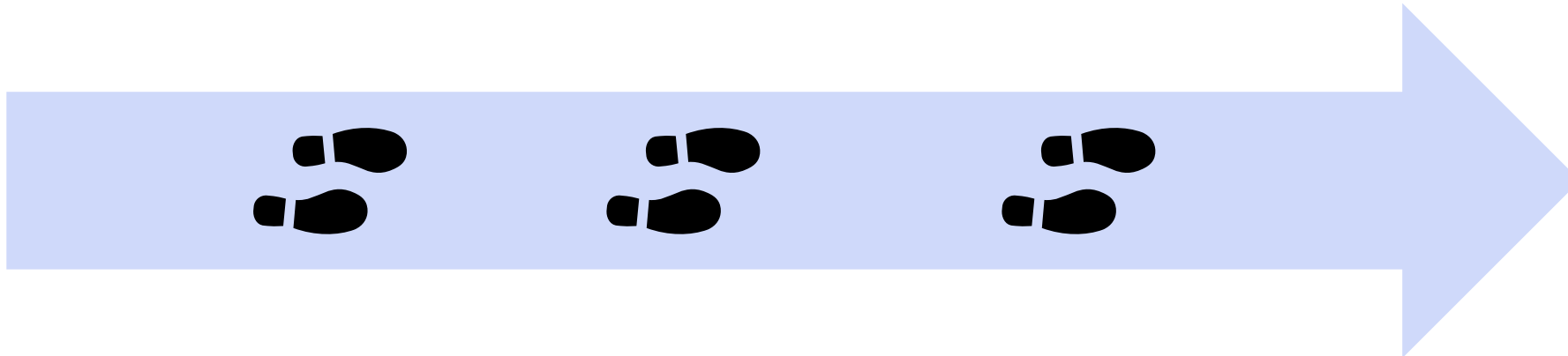
## Steps toward simple recommendations:

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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

# 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

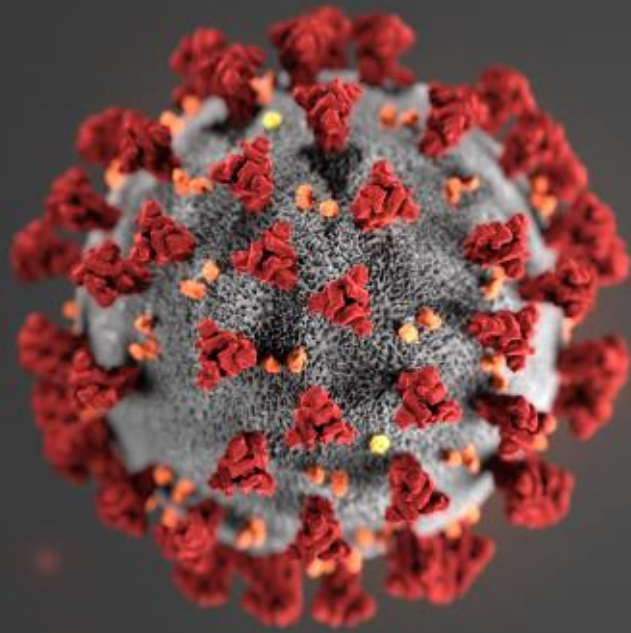
# Acknowledgments

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- 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)  
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.

