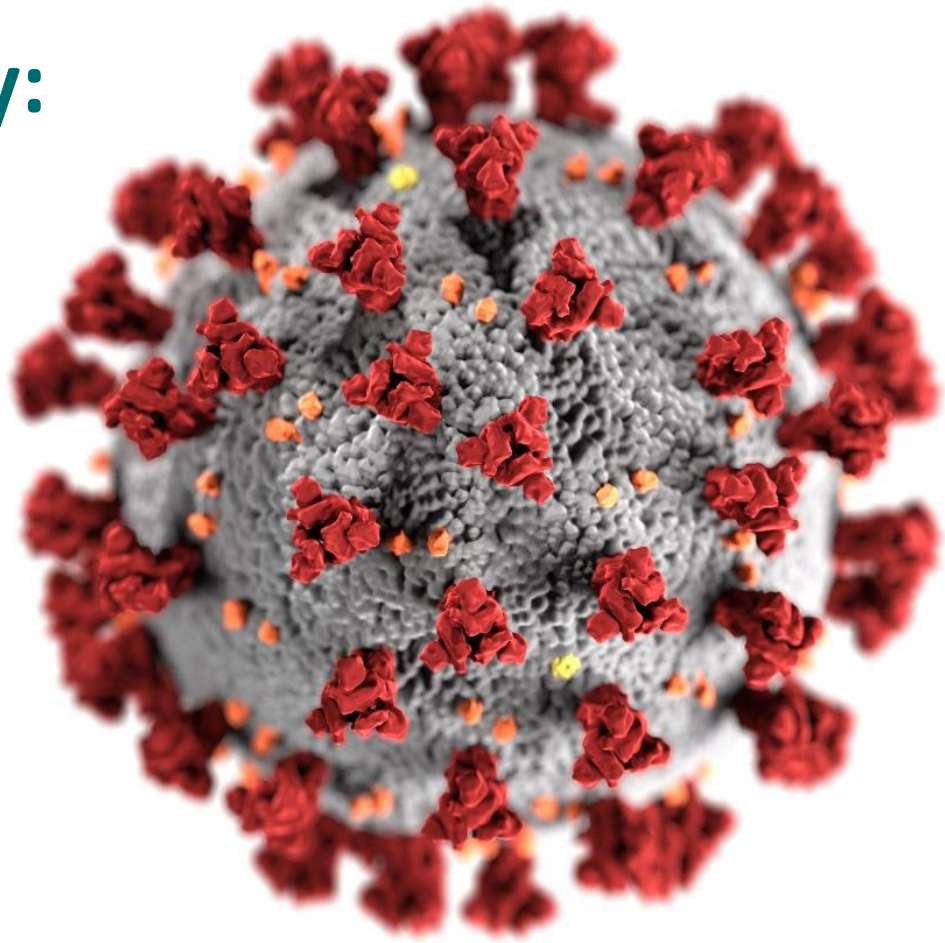
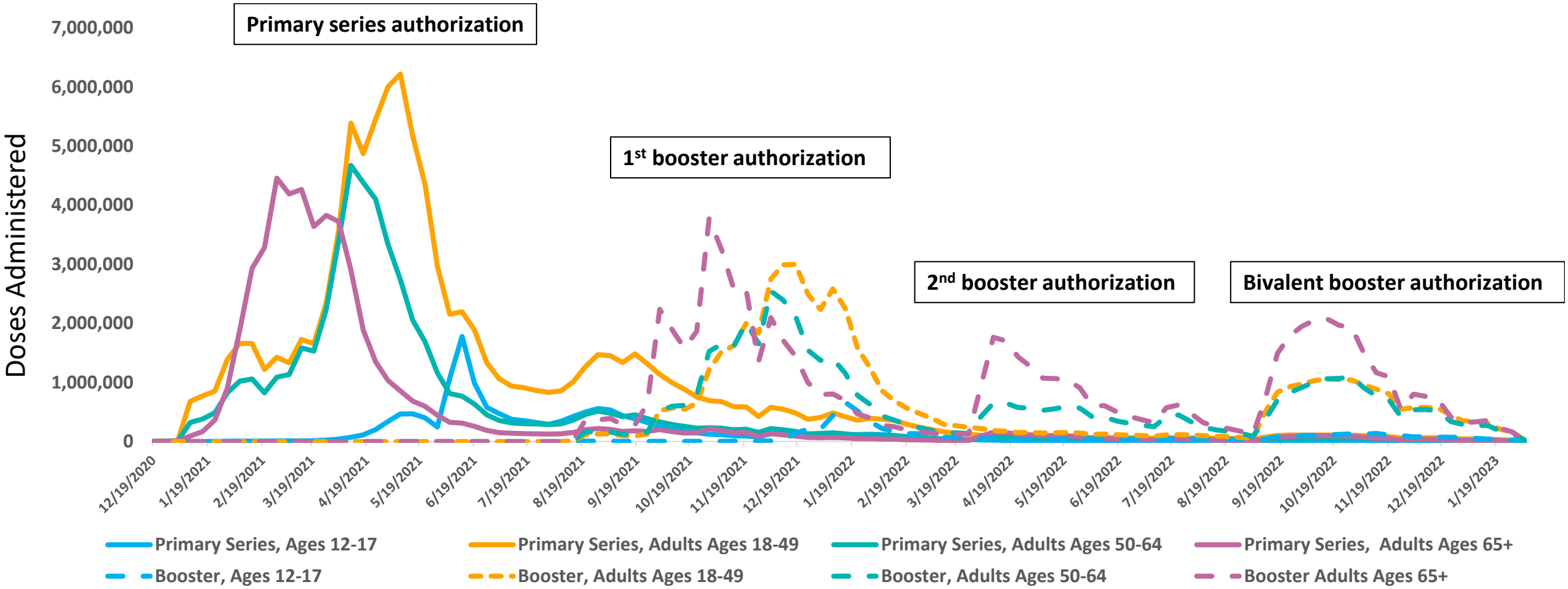
Updates to COVID-19 vaccine policy:
Considerations for Future Planning



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

cdc.gov/coronavirus

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

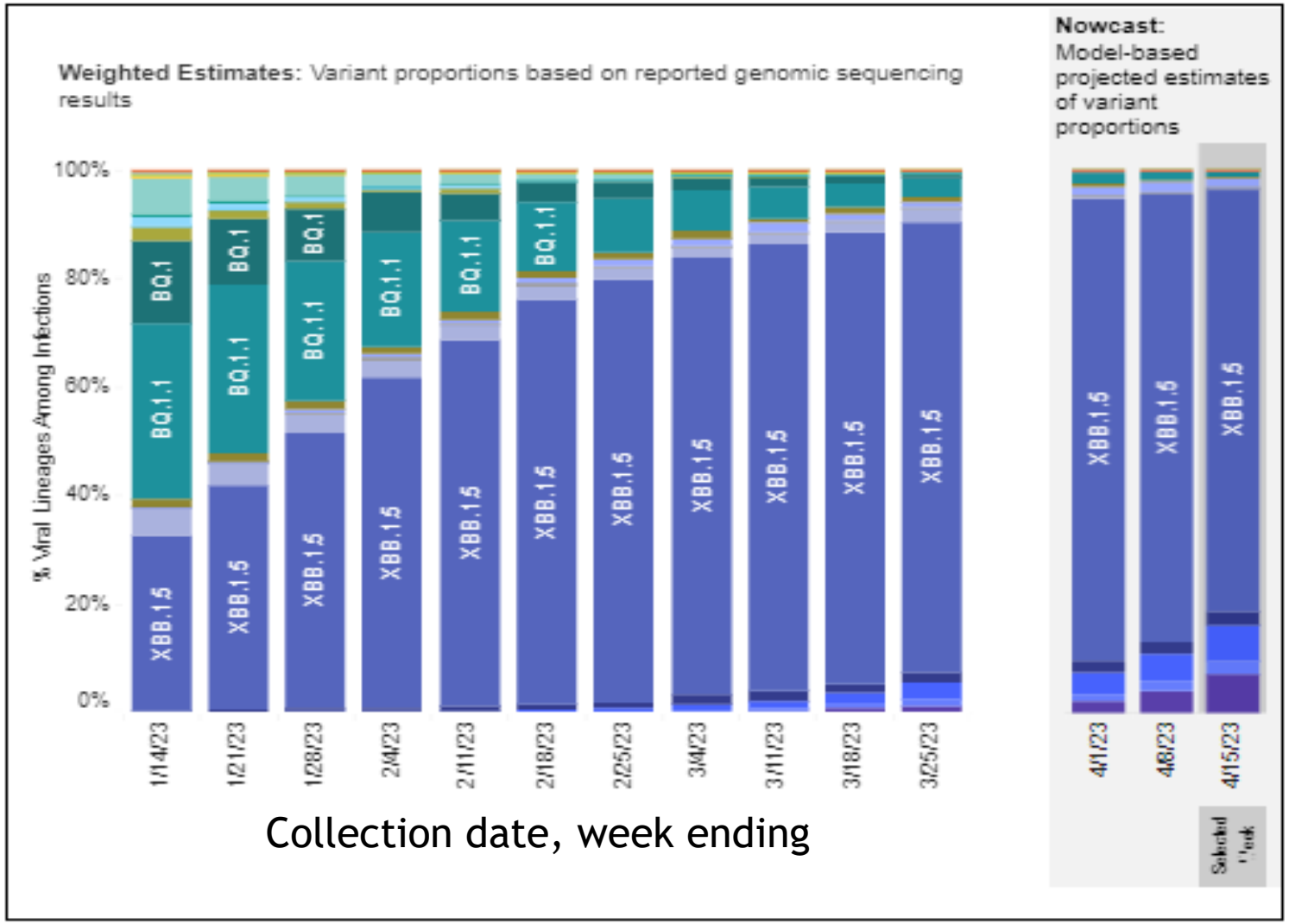
Coverage / Age (years)	<2	2-4	5-11	12-17	18-24	24-49	50-64	≥65
At least 1-dose†	8.6	10.7	39.9	72.1	82.2	85.4	95.0	95.0
Completed primary series	4.5	5.9	32.8	61.7	66.7	72.1	83.8	94.3
Bivalent booster	0.5	0.5	4.6	7.6	7.2	11.8	21.4	42.4
Unvaccinated	91.4	89.3	60.1	28.1	17.8	14.6	—†	—†

†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

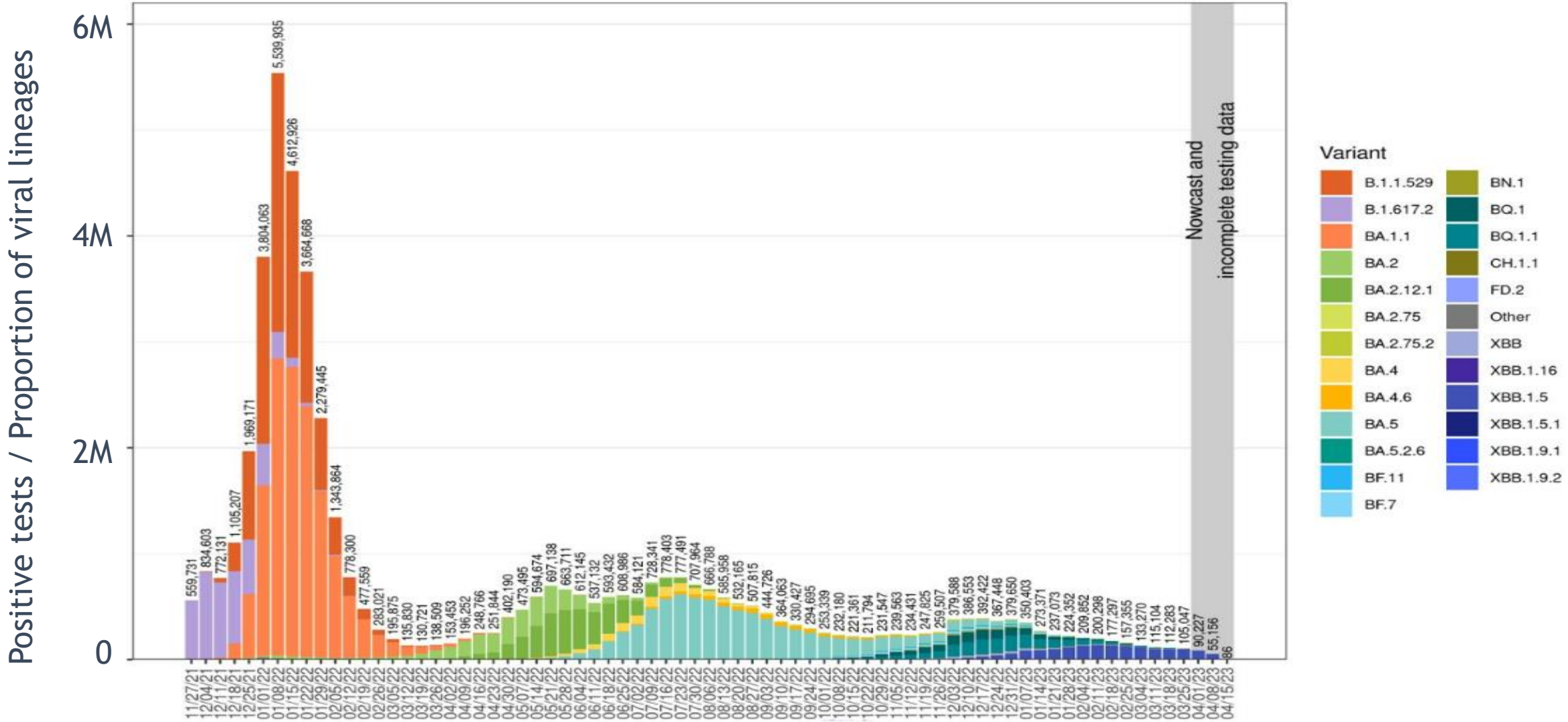


USA				
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	XBB.1.5	VOC	78.0%	73.6-81.8%
	XBB.1.16	VOC	7.2%	4.5-11.3%
	XBB.1.9.1	VOC	6.5%	4.8-8.8%
	XBB.1.9.2	VOC	2.5%	1.5-4.1%
	XBB.1.5.1	VOC	2.4%	1.8-3.1%
	FD.2	VOC	1.7%	0.9-3.2%
	BQ.1.1	VOC	1.0%	0.6-1.5%
	CH.1.1	VOC	0.3%	0.2-0.5%
	XBB	VOC	0.3%	0.2-0.3%
	BQ.1	VOC	0.1%	0.1-0.2%
	BN.1	VOC	0.0%	0.0-0.0%
	BA.5	VOC	0.0%	0.0-0.0%
	BA.2.75	VOC	0.0%	0.0-0.0%
	BF.7	VOC	0.0%	0.0-0.0%
	BA.2	VOC	0.0%	0.0-0.0%
	BA.1.1	VOC	0.0%	0.0-0.0%
	BA.5.2.6	VOC	0.0%	0.0-0.0%
	BF.11	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
	BA.4.6	VOC	0.0%	0.0-0.0%
Other	Other*		0.1%	0.0-0.1%

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

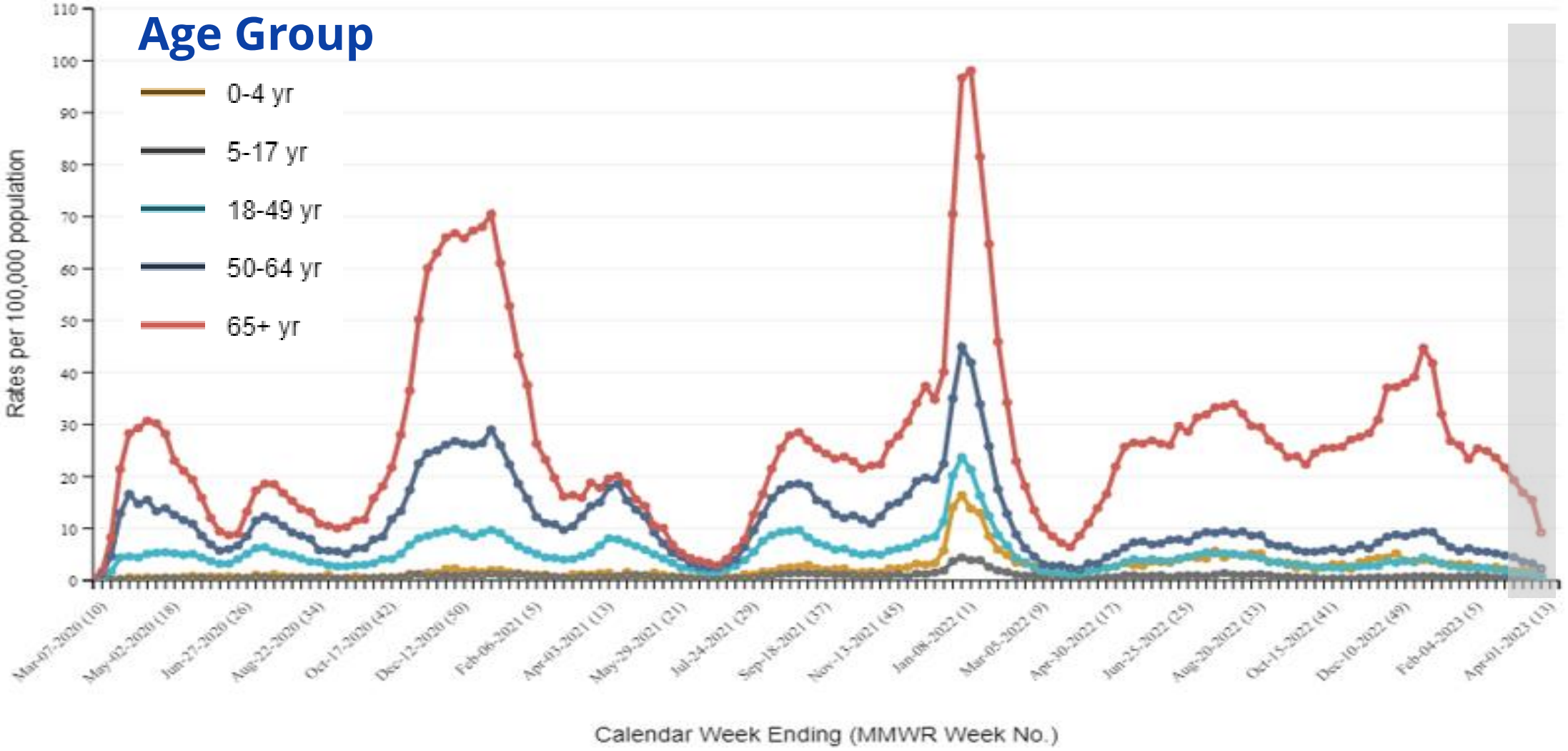
Estimated Number of Reported COVID-19 Cases by Variant

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

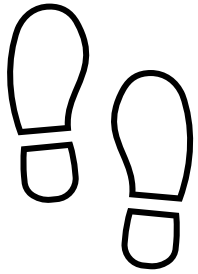
Weekly population-based rates of COVID-19-associated hospitalizations by age group— COVID-NET, March 2020–April 2023



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



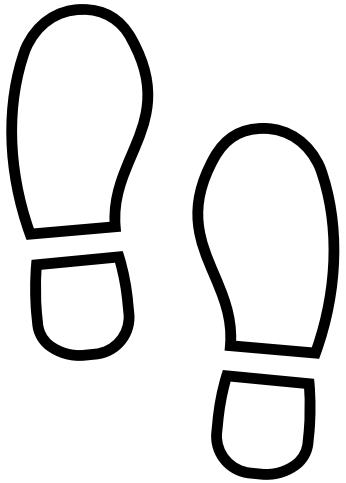
Steps toward simple recommendations:
Single formulation for mRNA COVID-19 vaccines
Single (possibly annual) dose for most individuals
Flexibility for vulnerable populations

COVID-19 vaccines: Where we are now

COVID-19 vaccines: Where we are going

Goal:
Simple recommendations

Updates to COVID-19 vaccine policy



<u>Steps toward simple recommendations</u>:

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

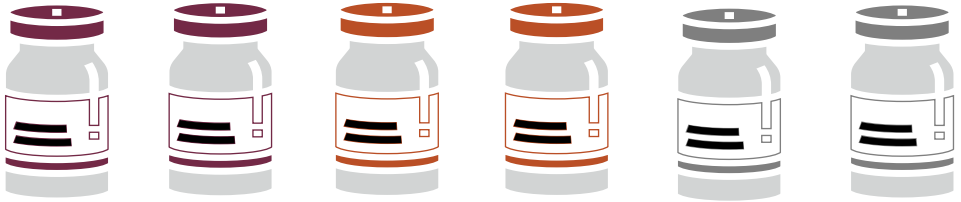
Benefits and Harms: Summary from previous ACIP meetings

- 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

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)

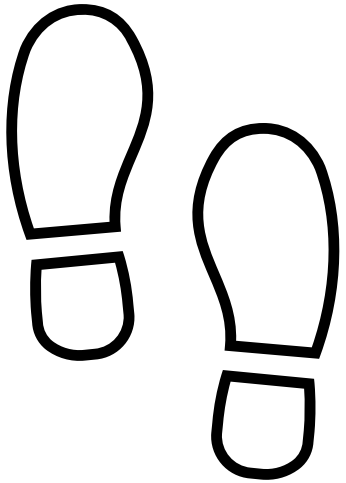
Single formulation for mRNA COVID-19 vaccines

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



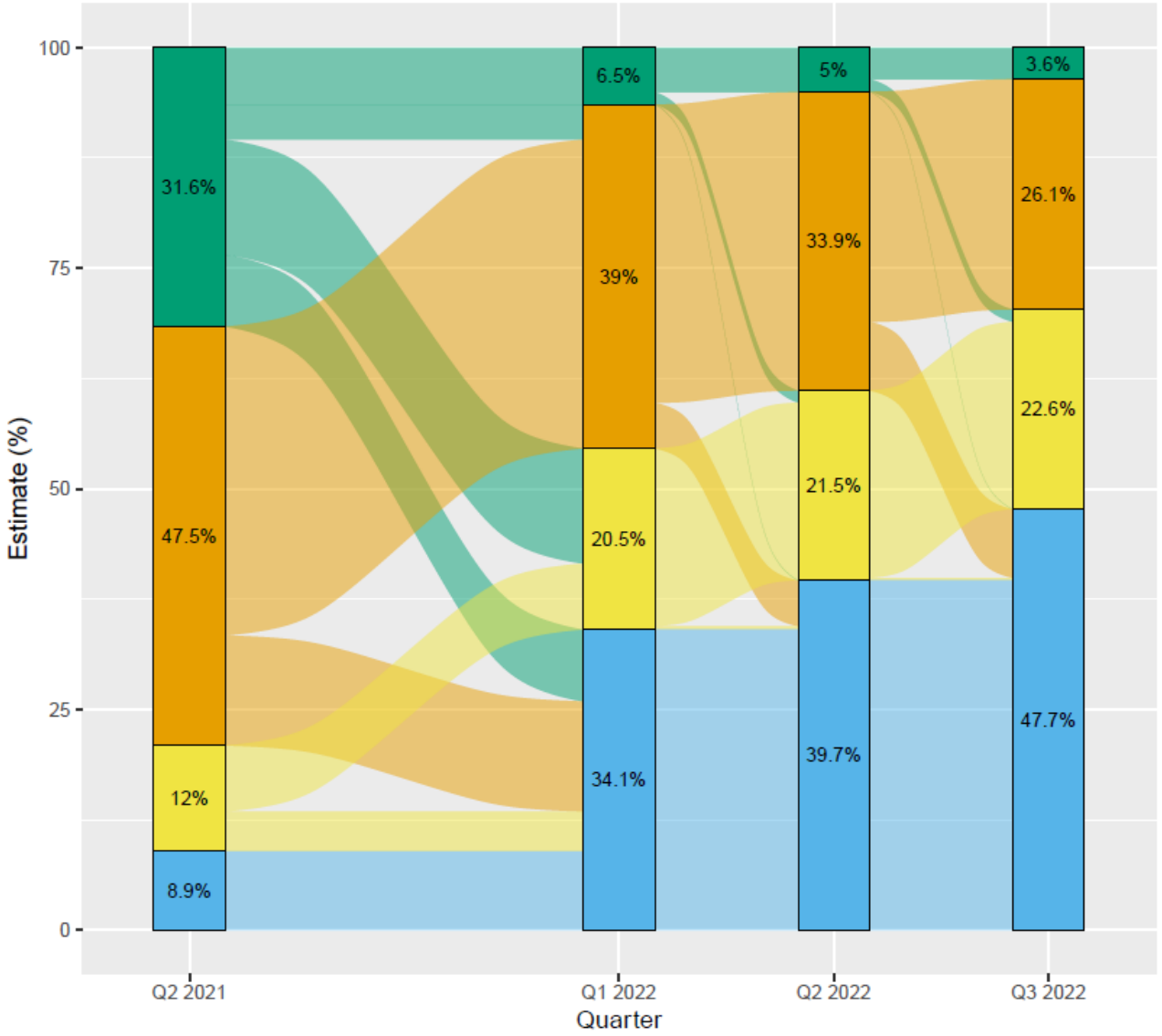
<u>Steps toward simple recommendations</u>:

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



No infection or vaccination

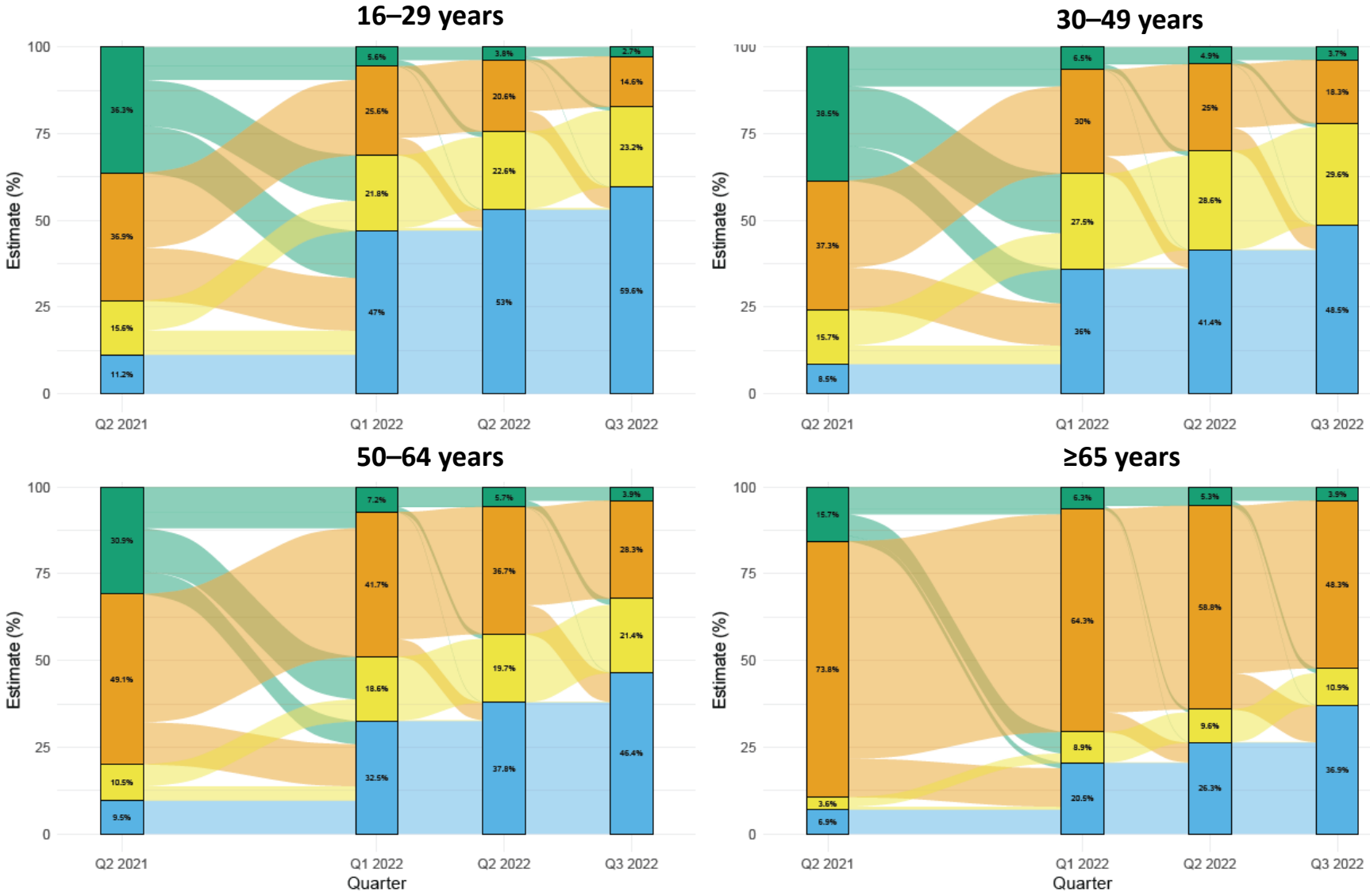
Vaccine only-induced antibodies

Infection only-induced antibodies

Both infection and vaccination-induced antibodies (hybrid immunity)

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



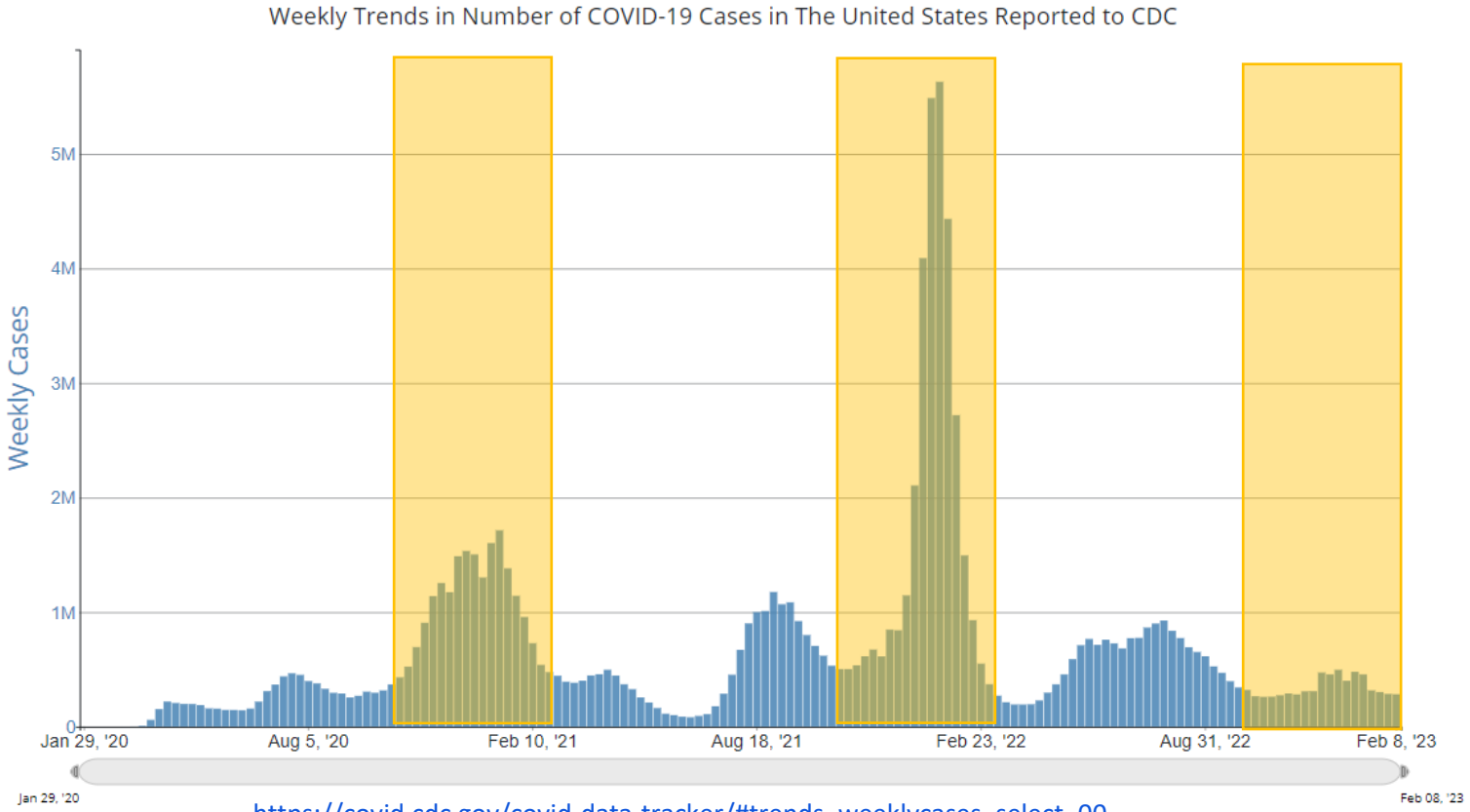
- No infection or vaccination
- Vaccination without previous infection
- Previous infection without vaccination
- Both previous infection and vaccination (hybrid immunity)

Source: CDC (unpublished)

How frequently should people get a COVID-19 vaccine?

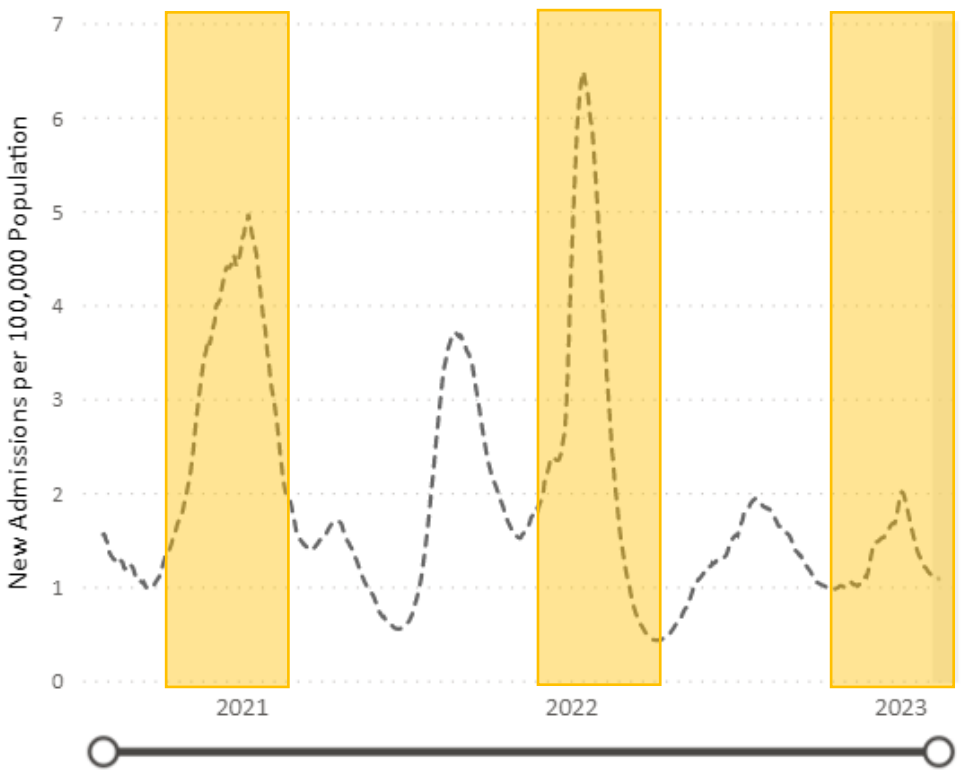
- Increases in COVID-19 cases (left) and hospitalizations (right) have occurred:
  - During the **winter months** and/or
  - Due to emergence of new **immune escape variants**

Cases from October 2021-February 2023 highlighted



https://covid.cdc.gov/covid-data-tracker/#trends_weeklycases_select_00

Admissions from October 2021 – February 2023 highlighted



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

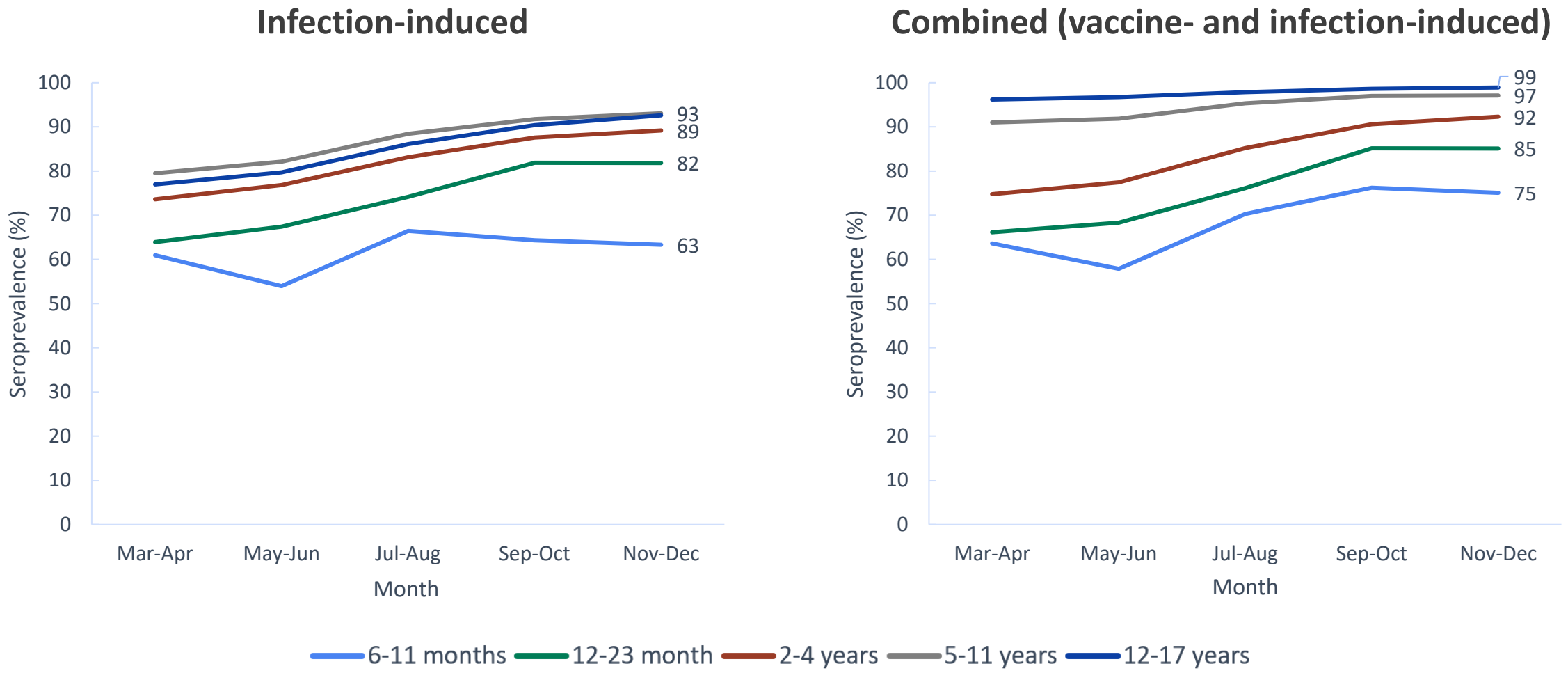
Updates from FDA authorizations

- 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



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

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

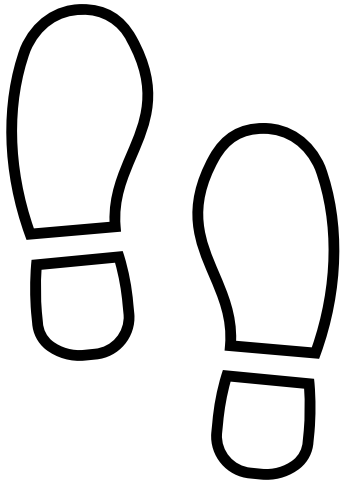
A **single bivalent dose** would be recommended for everyone ages 6 years and older

- 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



<u>Steps toward simple recommendations</u>:

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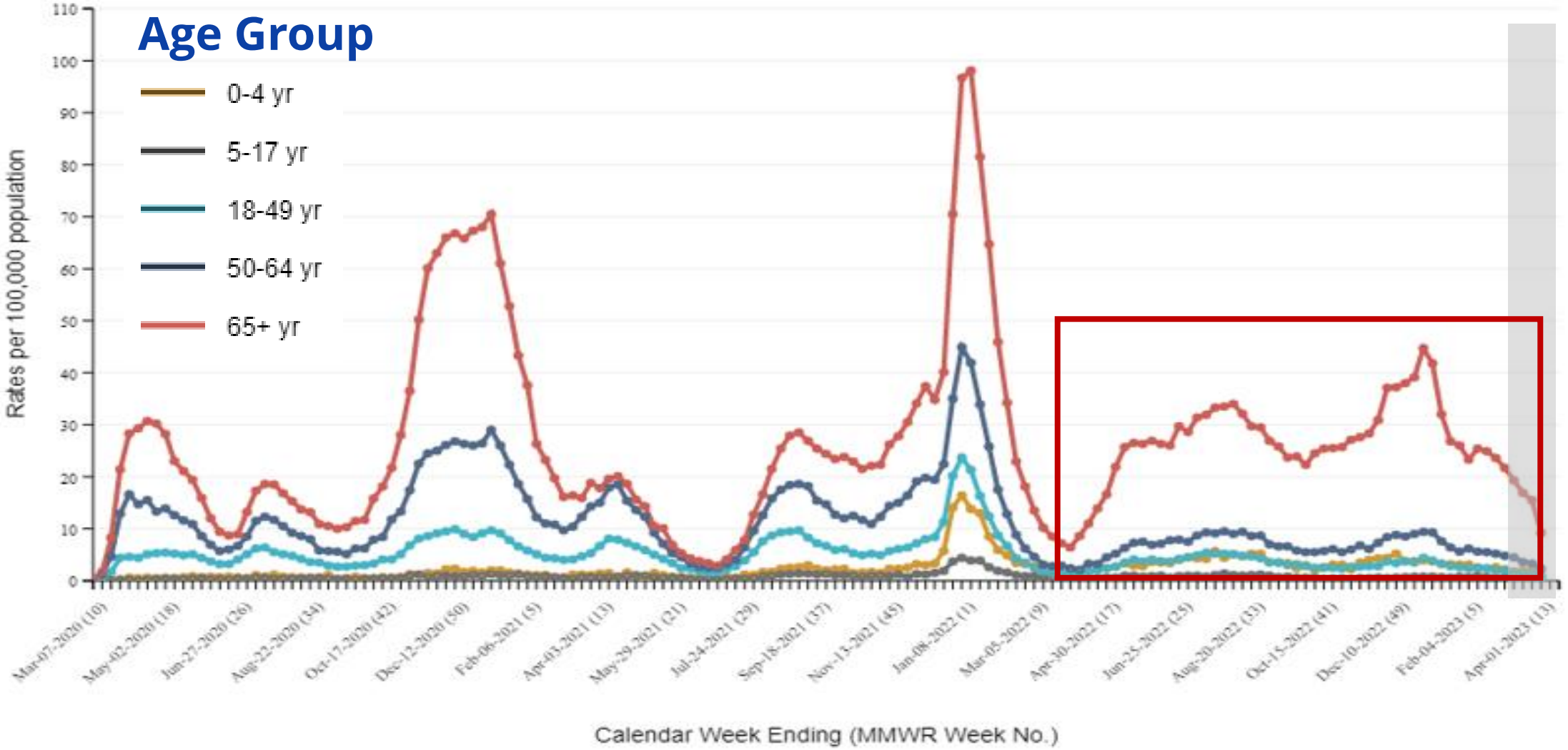
Single (annual?) dose for most individuals

Flexibility for vulnerable populations

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



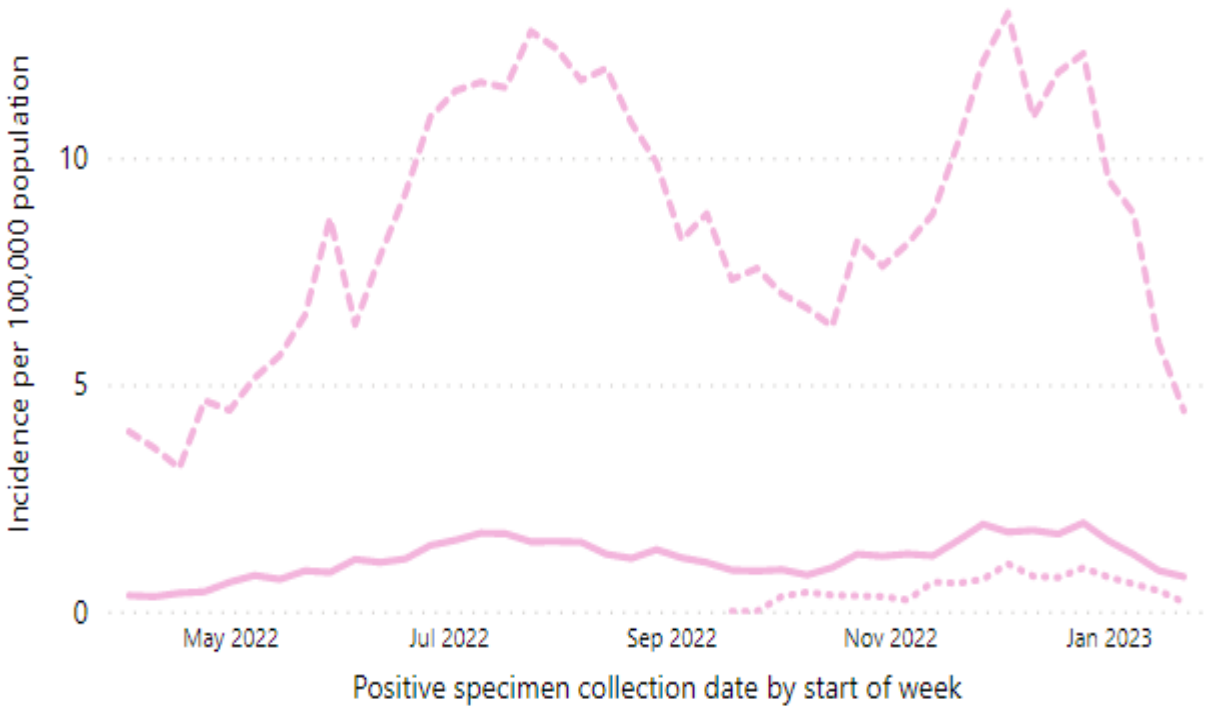
Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

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 —

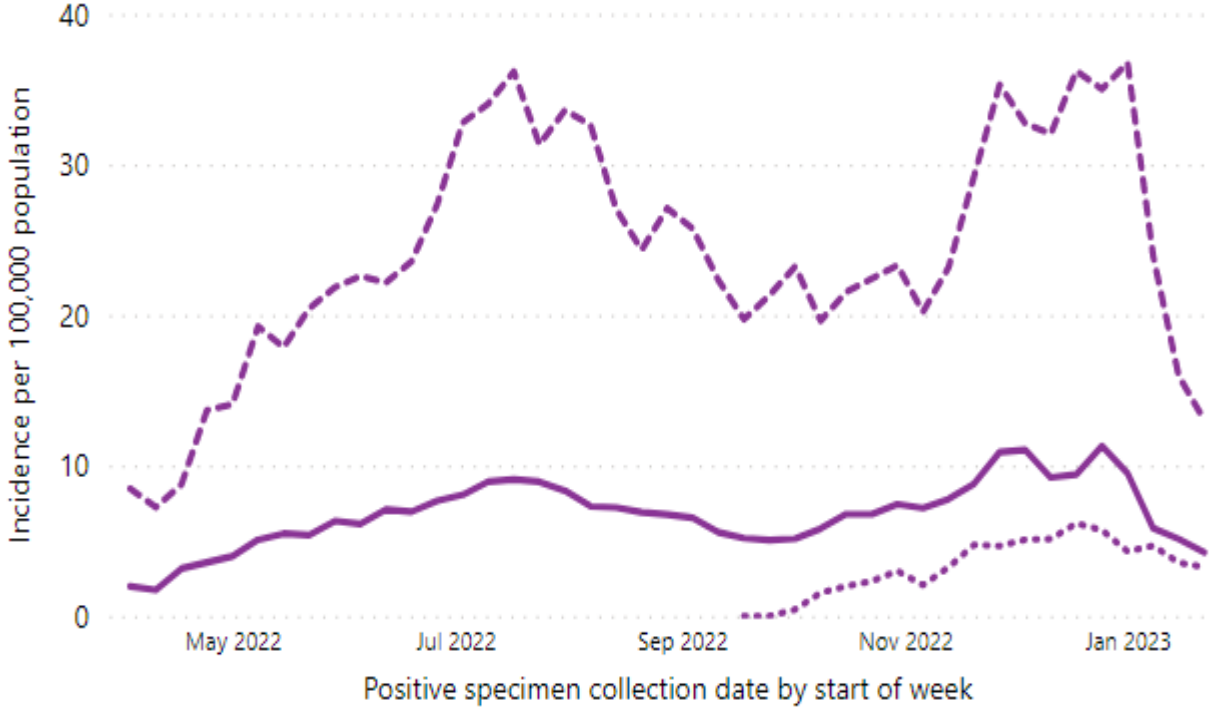
24 U.S. Jurisdictions, April 2022–January 2023

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

https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Accessed April 14, 2023

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

KFF COVID-19 Vaccine Monitor: January 2023. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-january-2023/ 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

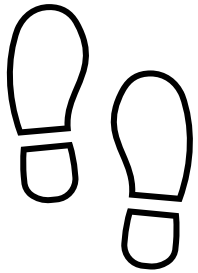
Implications for CDC recommendations

- 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**

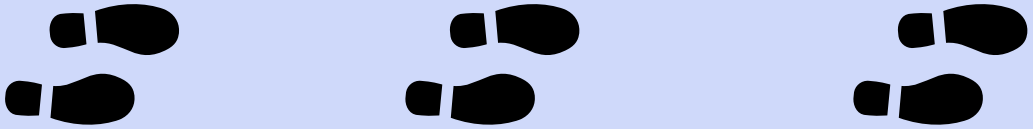
People who are immunocompromised may now **choose to receive** another updated COVID-19 vaccine dose -and-

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

Updates to COVID-19 vaccine policy

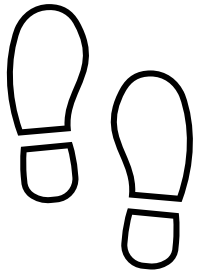


<u>Steps toward simple recommendations</u>:
Single formulation for mRNA COVID-19 vaccines
Single (possibly annual) dose for most individuals
Flexibility for vulnerable populations



<u>Goal</u>:
Simple recommendations

Updates to COVID-19 vaccine policy



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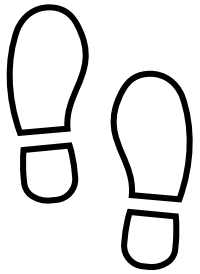
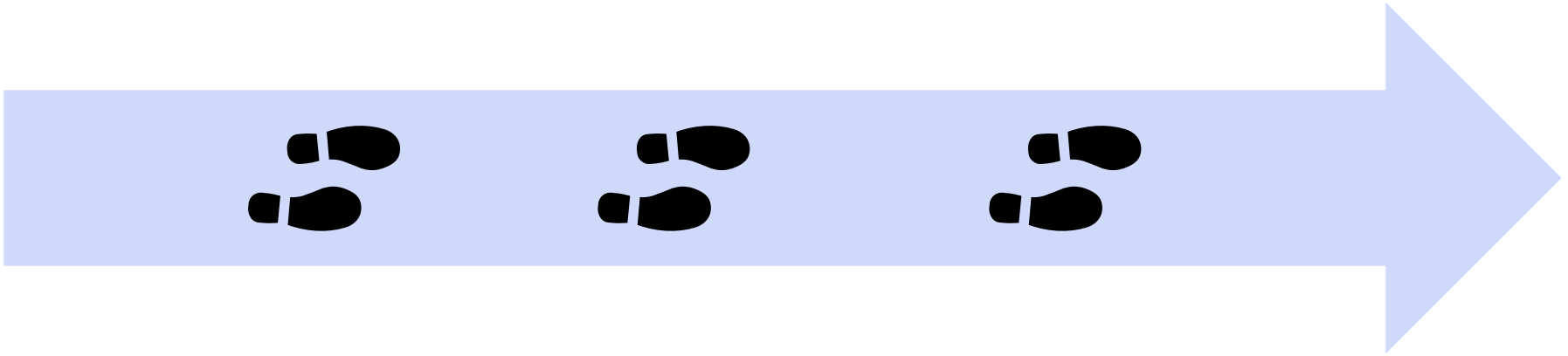


Future additional steps may be possible :
Simplifications for all COVID-19 vaccines
Possible updated vaccines this fall
Continue to evaluate data-driven ways to simplify pediatric program
Flexibility and simple guidance



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

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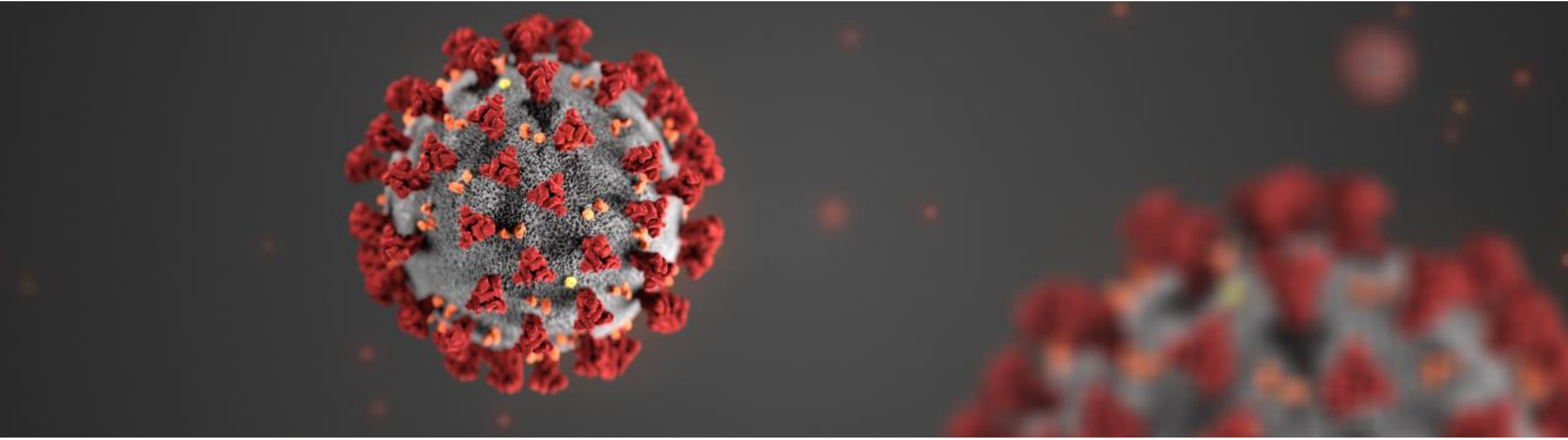
- Elisha Hall
- Valerie Morelli
- JoEllen Wolicki
- Heather Scobie
- Sierra Scarbrough
- Jefferson Jones
- Aron Hall
- Barbara Mahon
- Coronavirus and other Respiratory Viruses Division
- National Center for Immunization and Respiratory Diseases

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)
TTY: 1-888-232-6348 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.