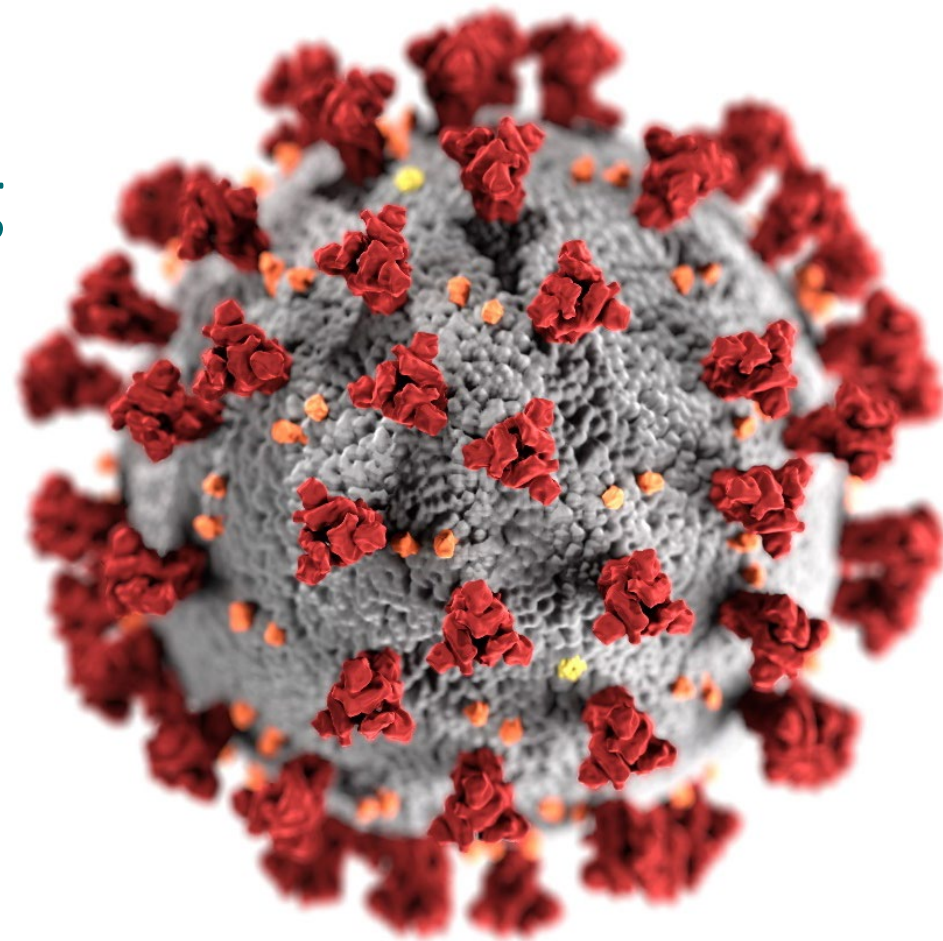


COVID-19 Vaccine: Considerations for Future Planning

Sara Oliver, MD, MSPH
ACIP Meeting
February 24, 2023



cdc.gov/coronavirus

Considerations for future planning

COVID-19 vaccines



COVID-19 vaccines:
Where we are now

COVID-19 vaccines:
Where we are going

Considerations for future planning

COVID-19 vaccines

COVID-19 vaccines:
Where we are now

How do we
get there?

COVID-19 vaccines:
Where we are going

Considerations for future planning COVID-19 vaccines

Where we are now:

Current recommendations
Vaccination rates
Hospitalization rates

COVID-19 vaccines:
Where we are now

COVID-19 vaccines:
Where we are going

Goal:
Simple
recommendations

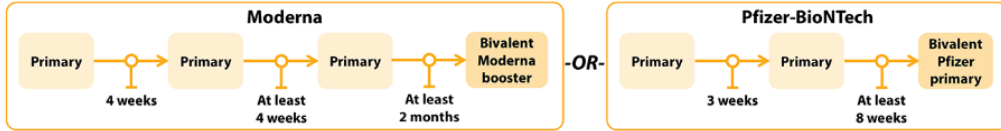
How we get there:

How frequently should people get a COVID-19 vaccine?
Are there groups/populations who should have >1 vaccine per year?

Current recommendations

COVID-19 Vaccination Schedule Infographic for People who ARE Moderately or Severely Immunocompromised

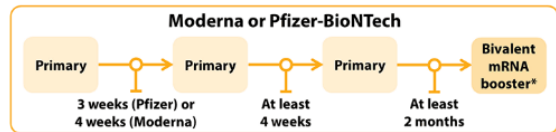
People ages 6 months through 4 years



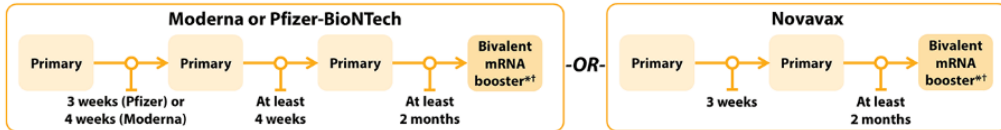
People age 5 years



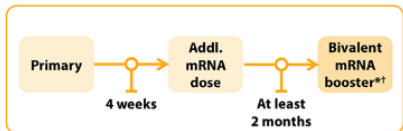
People ages 6 through 11 years



People ages 12 years and older

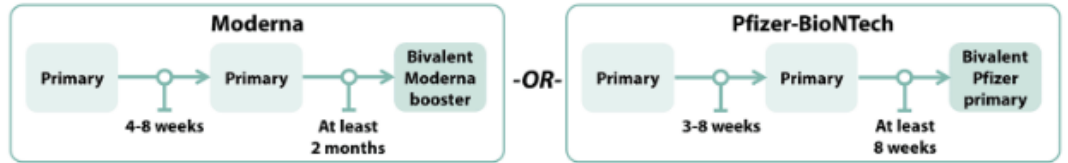


People ages 18 years and older who previously received Janssen primary series dose‡

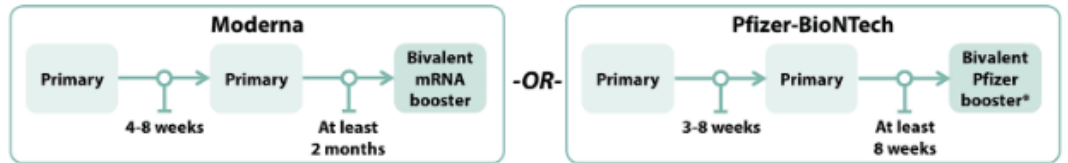


COVID-19 Vaccination Schedule Infographic for People who are NOT Moderately or Severely Immunocompromised

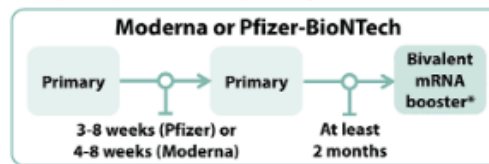
People ages 6 months through 4 years



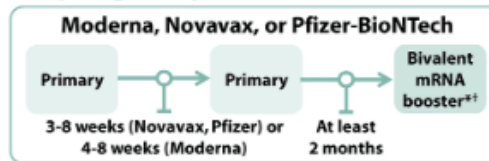
People age 5 years



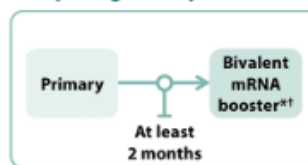
People ages 6 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose‡



*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.
 †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.
 ‡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>

*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.
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 ‡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>

U.S. COVID-19 Vaccination Coverage (%) of Total Population by Age Group — February 8, 2023

Coverage / Age (years)	<2	2-4	5-11	12-17	18-24	24-49	50-64	≥65
At least 1-dose†	7.6	10.3	39.7	71.9	81.9	85.2	95.0	95.0
Completed primary series	3.7	5.5	32.6	61.6	66.5	72.0	83.7	94.2
1st monovalent booster*	-	-	3.3	16.6	27.2		45.3	64.6
2nd monovalent booster *	-	-	-	-	-	-	10.6	25.3
Bivalent booster**	0.2	0.3	4.0	7.0	6.7	11.2	20.3	40.8
Unvaccinated	92.4	89.7	60.3	28.1	18.1	14.8	—†	—†

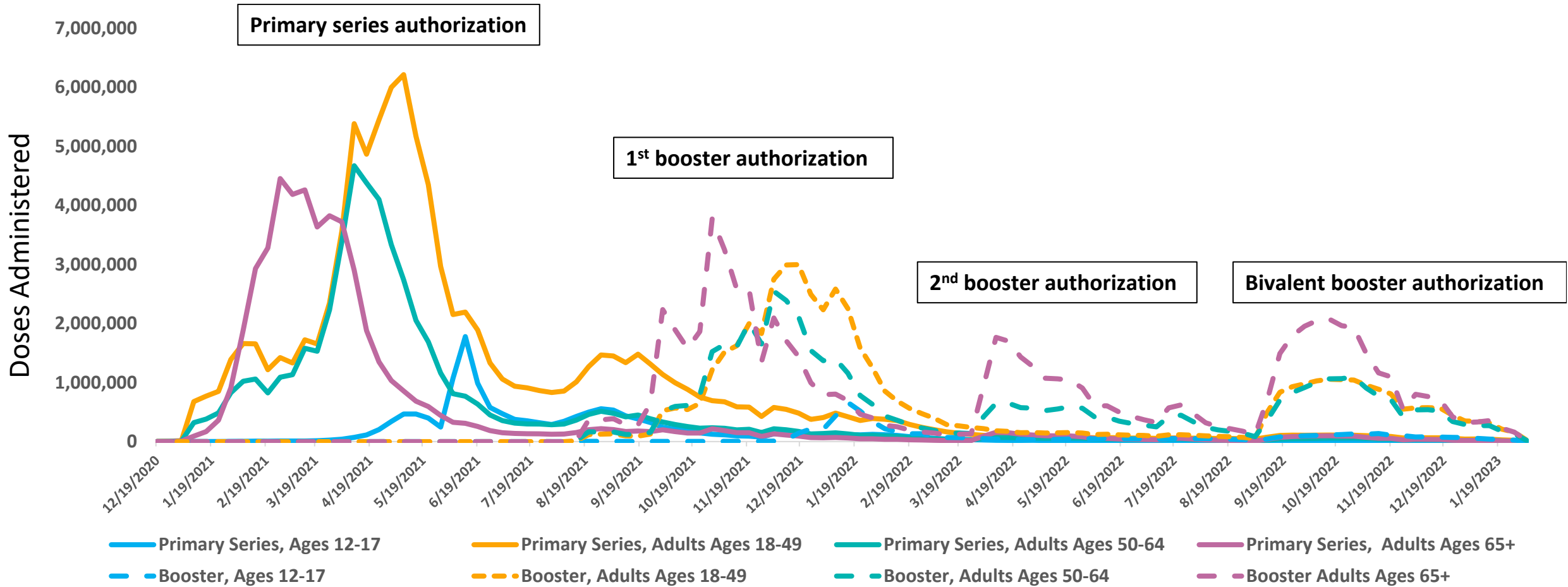
*Monovalent booster dose coverage as of August 26, 2022

** Bivalent booster coverage is independent of 1st and 2nd dose monovalent coverage

†Note: Coverage is capped at 95%

Source: <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends> Updated February 10, 2023

U.S. COVID-19 vaccine uptake by age group, August 2021-January 2023



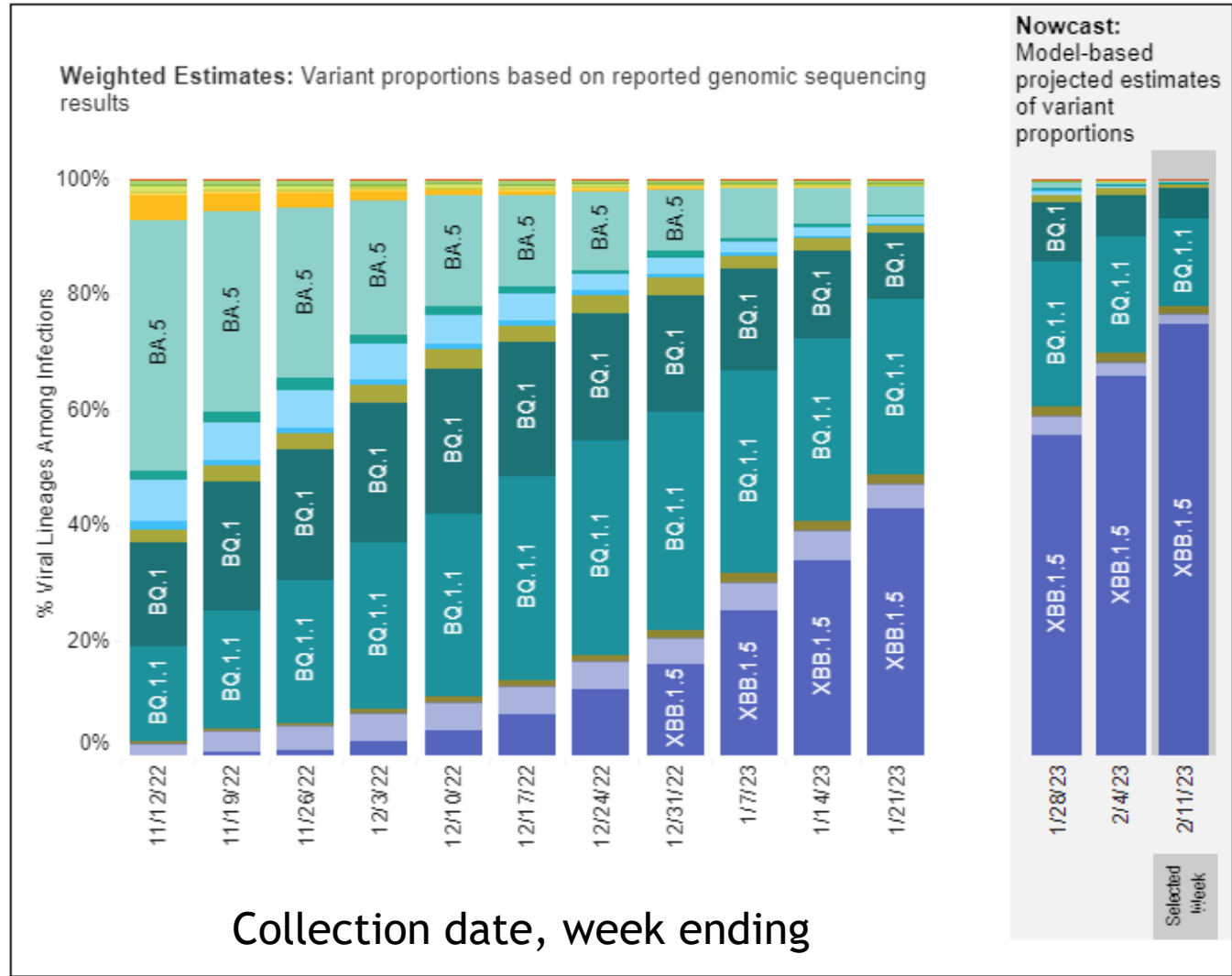
COVID-19 message fatigue challenges vaccine uptake

- Recent studies reflect profound COVID-19 message fatigue¹, desire to end use of mitigation², and a common perception among adults that immunity is sufficient without further boosters³
- Barriers to vaccine access persist for some populations, including but not limited to:
 - People living in rural areas⁴
 - People experiencing homelessness⁵
 - People with disabilities⁶
 - *"If I can't get to it, it doesn't exist for me."*
- Despite improvements in vaccine equity after primary series vaccination, disparities in booster coverage have emerged⁷

1. Guan et al. Health Communication 2022: COVID-19 Message Fatigue: How Does It Predict Preventive Behavioral Intentions and What Types of Information are People Tired of Hearing About? - PubMed (nih.gov) 2. CDC's State of Vaccine Confidence Insights Reports, Jan 26 2023: [CDC's State of Vaccine Confidence Insights Report](#) 3. Sinclair et al. MMWR Jan 20 2023: MMWR, Reasons for Receiving or Not Receiving Bivalent COVID-19 Booster Vaccinations Among Adults — United States, November 1–December 10, 2022 (cdc.gov) 4. Assessing barriers to access and equity for COVID-19 vaccination in the US - PMC (nih.gov) 5. McCosker et al. Vaccine May 2022: Strategies to improve vaccination rates in people who are homeless. 6. Griffin-Blake et al. Barriers and facilitators of COVID-19 vaccine uptake among people with disabilities. Presentation to the COVID-19 Vaccine Innovation Team: Feb 8 2023. 7. [COVID-19 Vaccination Coverage, by Race and Ethnicity — National Immunization Survey Adult COVID Module, United States, December 2020–November 2021 | MMWR \(cdc.gov\)](#)

Trends in weighted variant proportion estimates & Nowcast

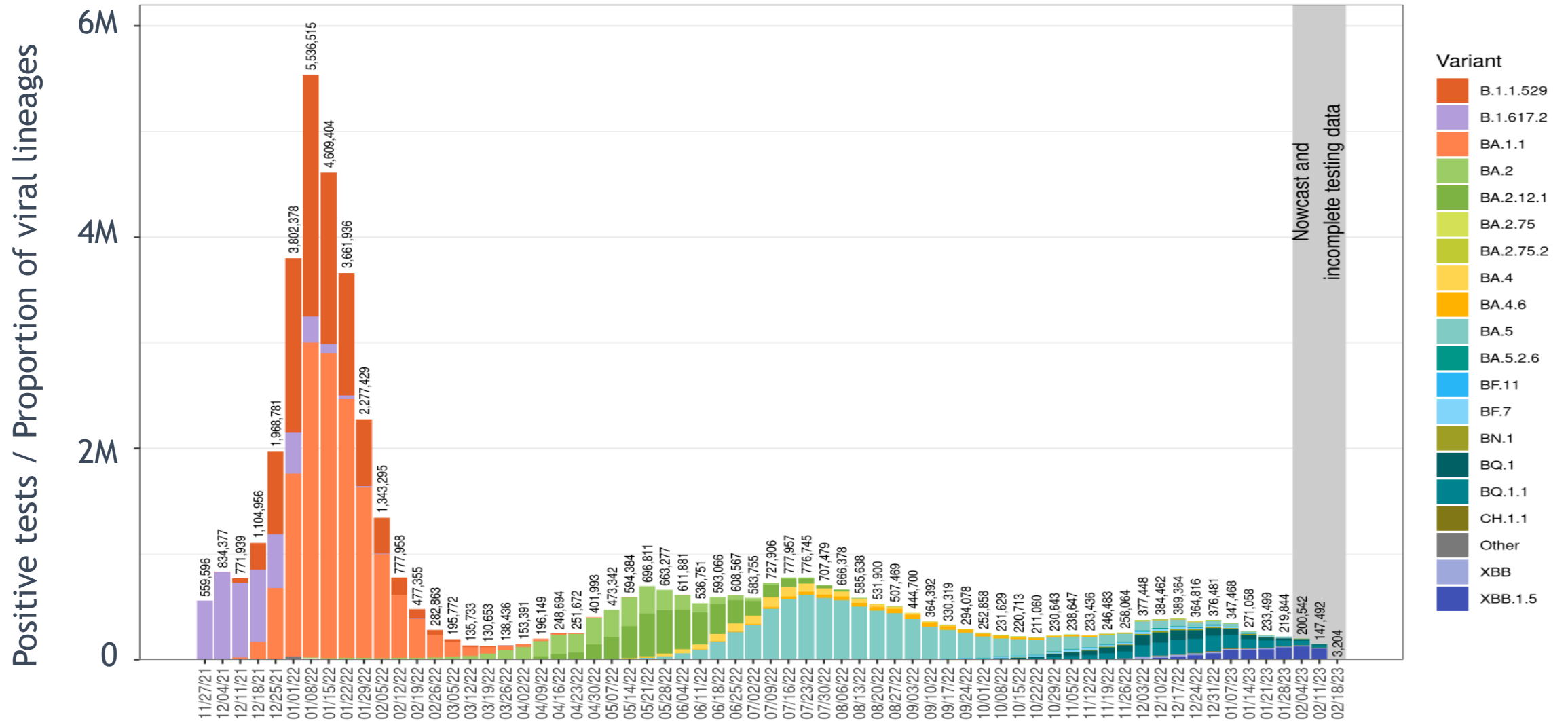
United States, November 6, 2022-February 11, 2023



USA				
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	XBB.1.5	VOC	74.7%	67.0-81.2%
	BQ.1.1	VOC	15.3%	11.4-20.2%
	BQ.1	VOC	5.1%	3.7-6.8%
	XBB	VOC	1.9%	1.4-2.5%
	CH.1.1	VOC	1.3%	0.9-1.9%
	BN.1	VOC	0.8%	0.5-1.1%
	BA.5	VOC	0.3%	0.2-0.5%
	BF.7	VOC	0.3%	0.2-0.4%
	BA.5.2.6	VOC	0.1%	0.1-0.2%
	BA.2	VOC	0.1%	0.0-0.1%
	BF.11	VOC	0.0%	0.0-0.1%
	BA.2.75	VOC	0.0%	0.0-0.0%
	BA.2.75.2	VOC	0.0%	0.0-0.0%
	BA.4.6	VOC	0.0%	0.0-0.0%
B.1.1.529	VOC	0.0%	0.0-0.0%	
BA.2.12.1	VOC	0.0%	0.0-0.0%	
BA.4	VOC	0.0%	0.0-0.0%	
BA.1.1	VOC	0.0%	0.0-0.0%	
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.1%	0.0-0.1%

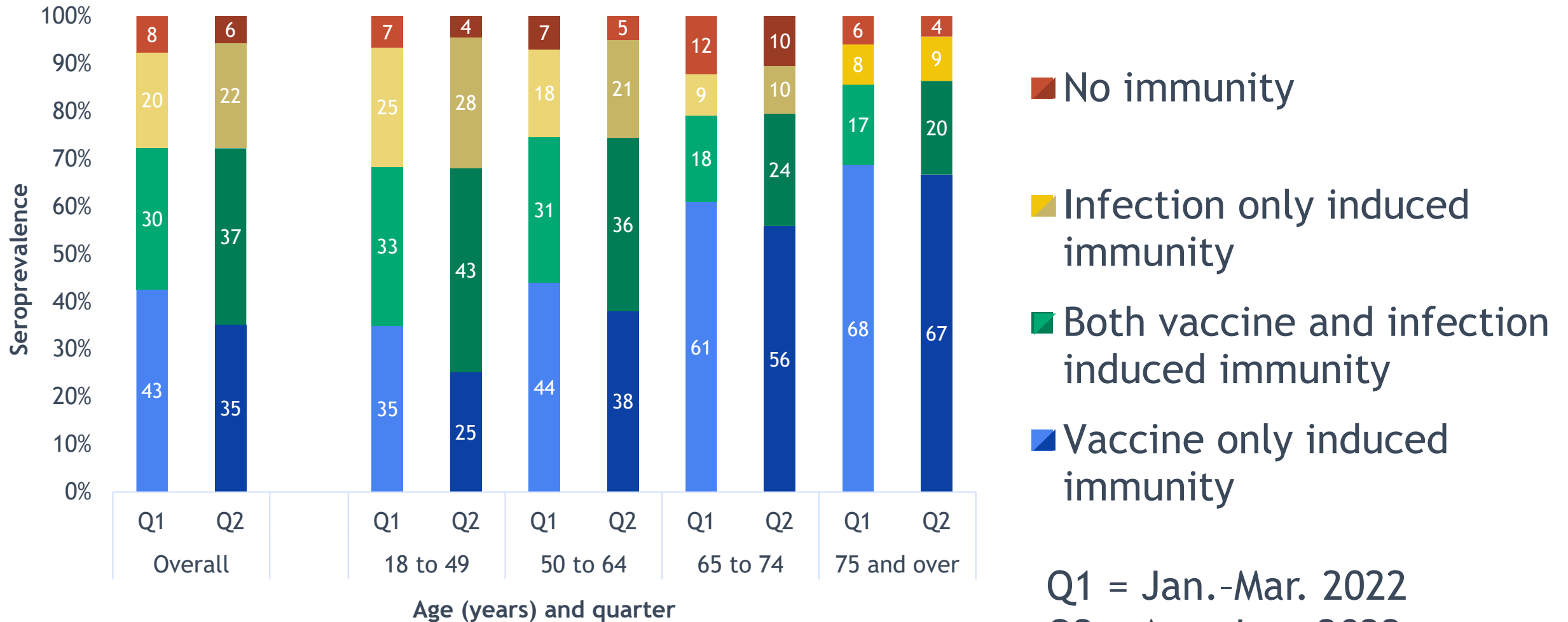
Estimated Number of Reported COVID-19 Cases by Variant

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

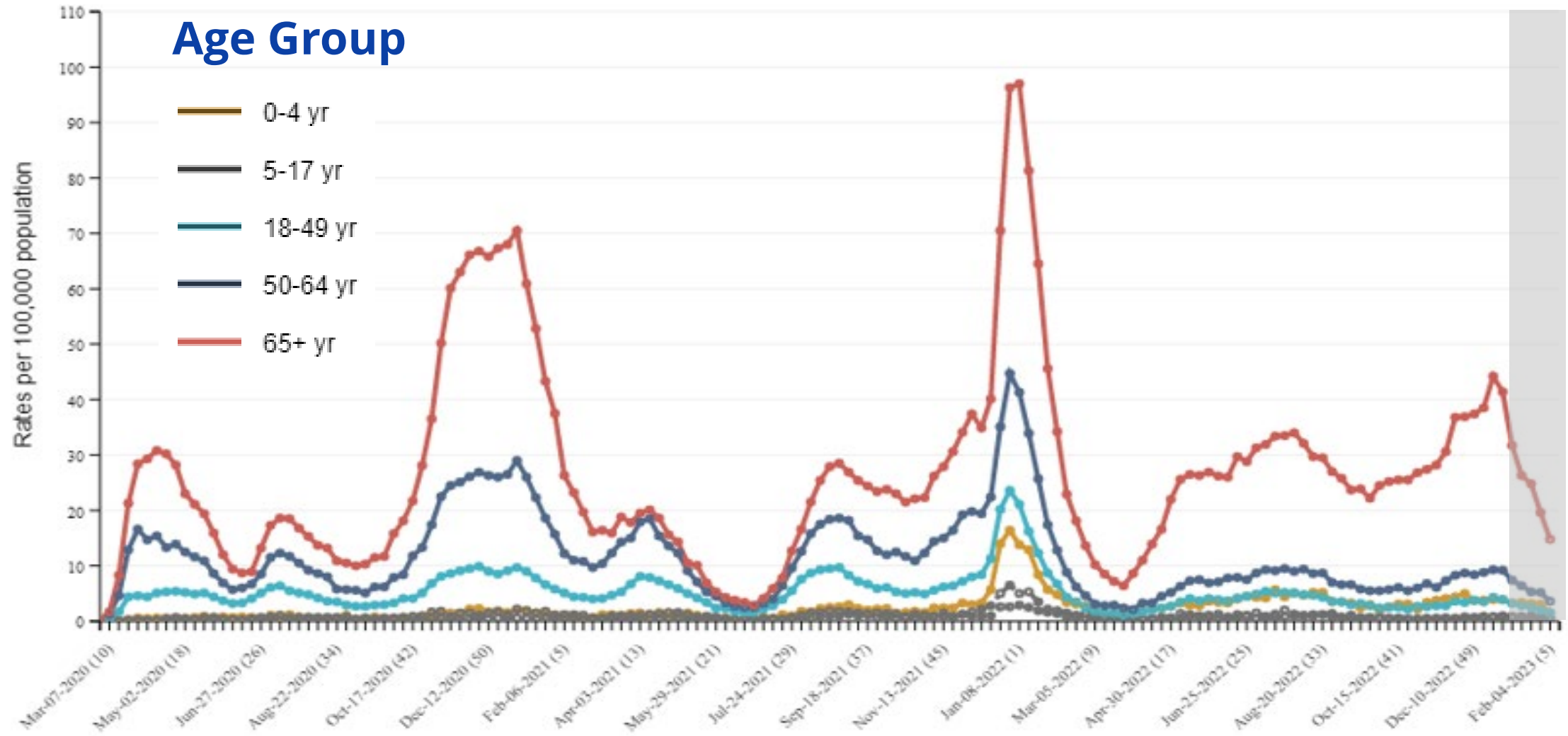


CDC COVID-19 Lab Coordinating Unit Strain Surveillance and Emerging Variant Group. Data sources: <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> and https://covid.cdc.gov/covid-data-tracker/#trends_newtestresultsreported_7daytestingpositive_00

Seroprevalence by Vaccine and Infection History Among Adult U.S. Blood Donors, January-June 2022

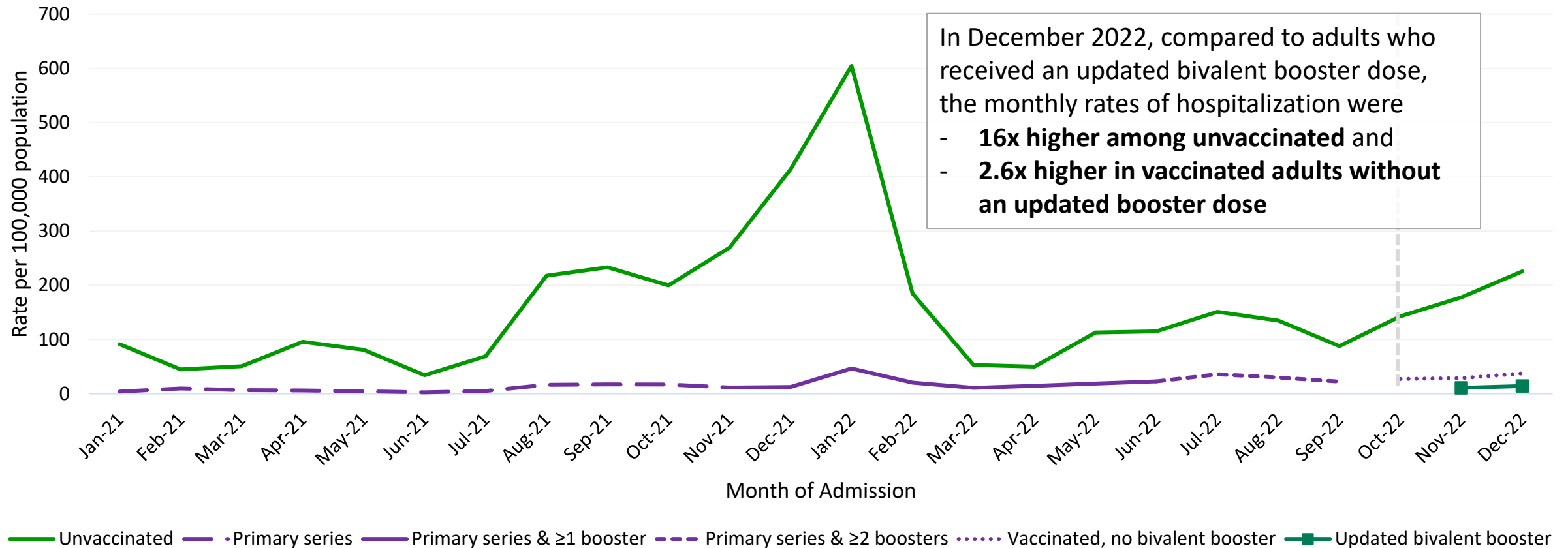


Weekly population-based rates of COVID-19-associated hospitalizations by age group— COVID-NET, March 2020–February 2023



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

Monthly Age-Adjusted Rates of Lab-Confirmed Hospitalizations by Vaccination Status among Adults Ages ≥18 Years — COVID-NET, January 2021–December 2022



Data are based on all hospitalizations regardless of reason for admission. **Unvaccinated:** No recorded doses of COVID-19 vaccine. **Primary series ± ≥1 booster:** Completed a primary series with or without ≥1 booster dose but did not receive an updated bivalent booster dose. **Vaccinated, but no bivalent booster:** Completed a primary series with or without ≥1 booster dose but did not receive an updated bivalent booster dose. **Updated bivalent booster:** Received updated bivalent booster dose. Persons with partial or unknown vaccination status are excluded. See <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination> for complete definitions of vaccination categories.

COVID-19 vaccine

Where we are now

- Current COVID-19 vaccine recommendations are **complex**
- Uptake of current bivalent vaccine is **low**
- SARS-CoV-2 continues to evolve, but recent virus evolution has not led to large population-level surges in cases or hospitalizations
- Most adults have a prior infection, prior vaccination, or both
- Hospitalization rates are highest **older adults**, but remain **low** among people who have received a **bivalent booster**

Considerations for future planning COVID-19 vaccines

COVID-19 vaccines:
Where we are now

COVID-19 vaccines:
Where we are going

Goal:
Simple
recommendations

How we get there:

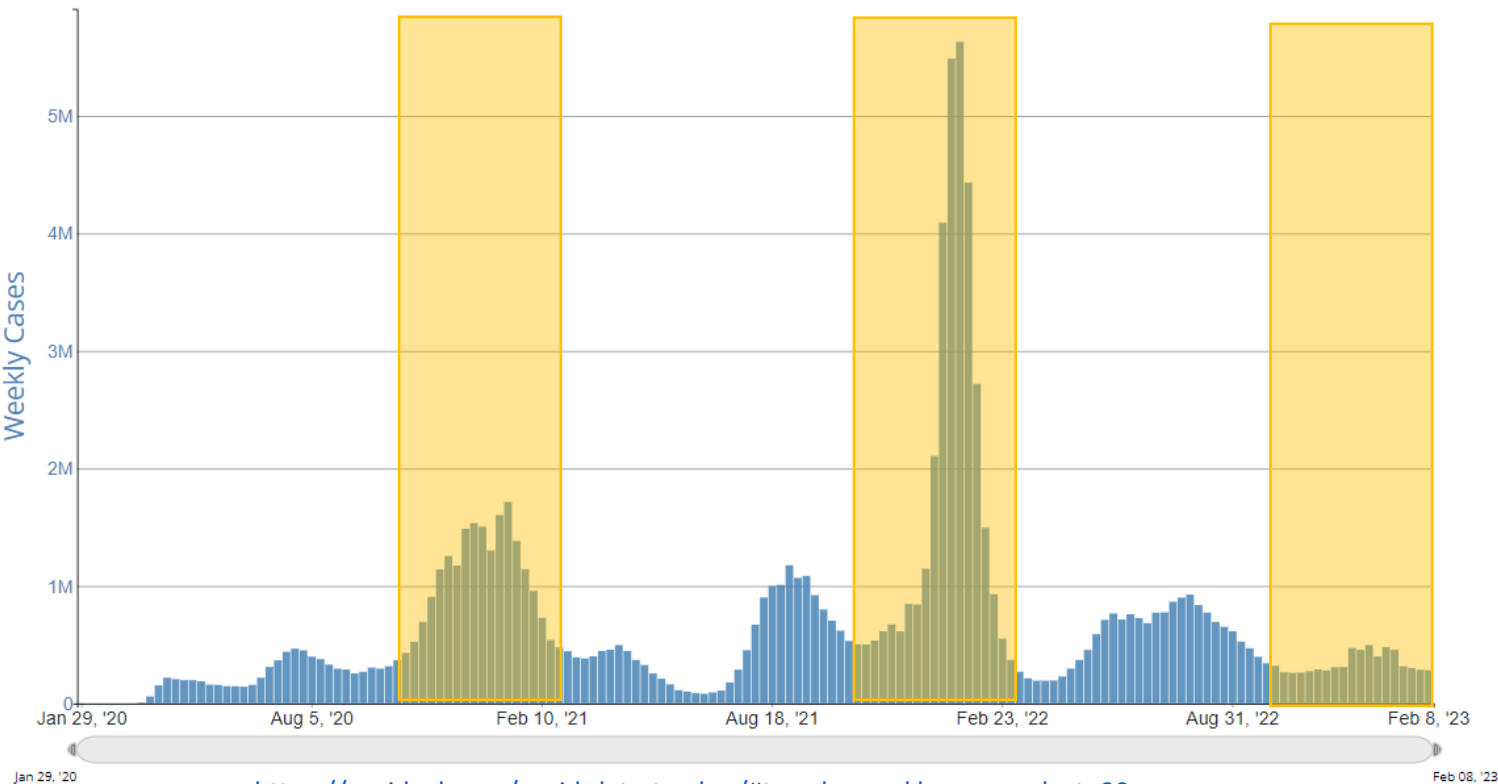
How frequently should people get a COVID-19 vaccine?
Are there groups/populations who should have >1 vaccine per year?

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 development of new **immune escape variant**

Cases from October 2021-February 2023 highlighted

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

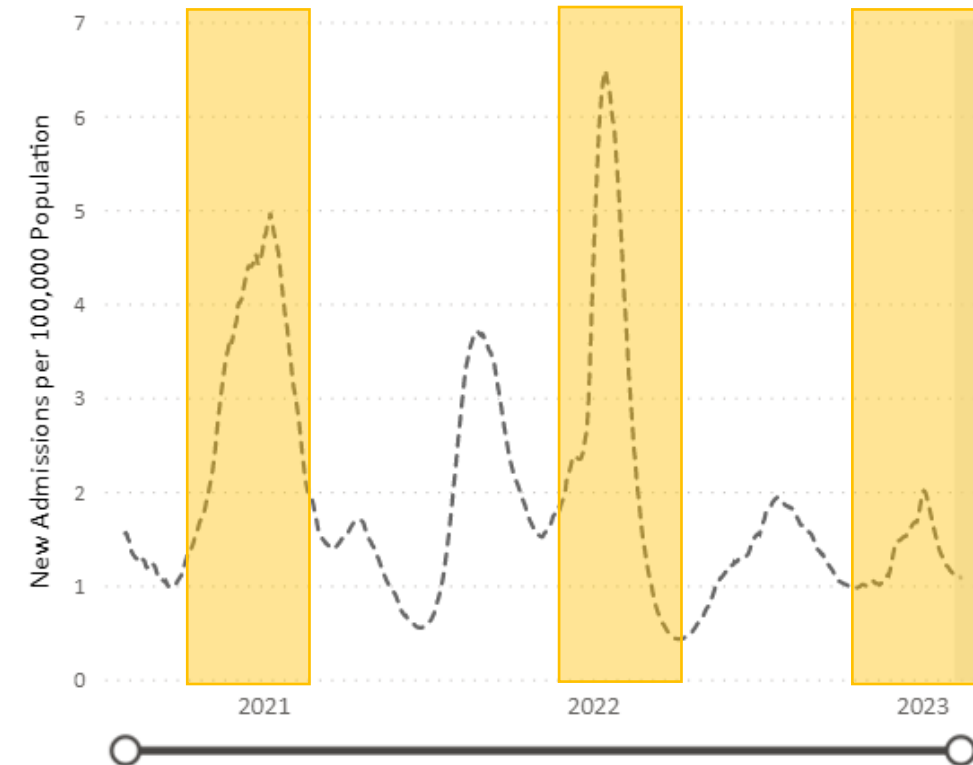


<https://covid.cdc.gov/covid-data-tracker/#trends weeklycases select 00>

Admissions from October 2021 – February 2023 highlighted

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

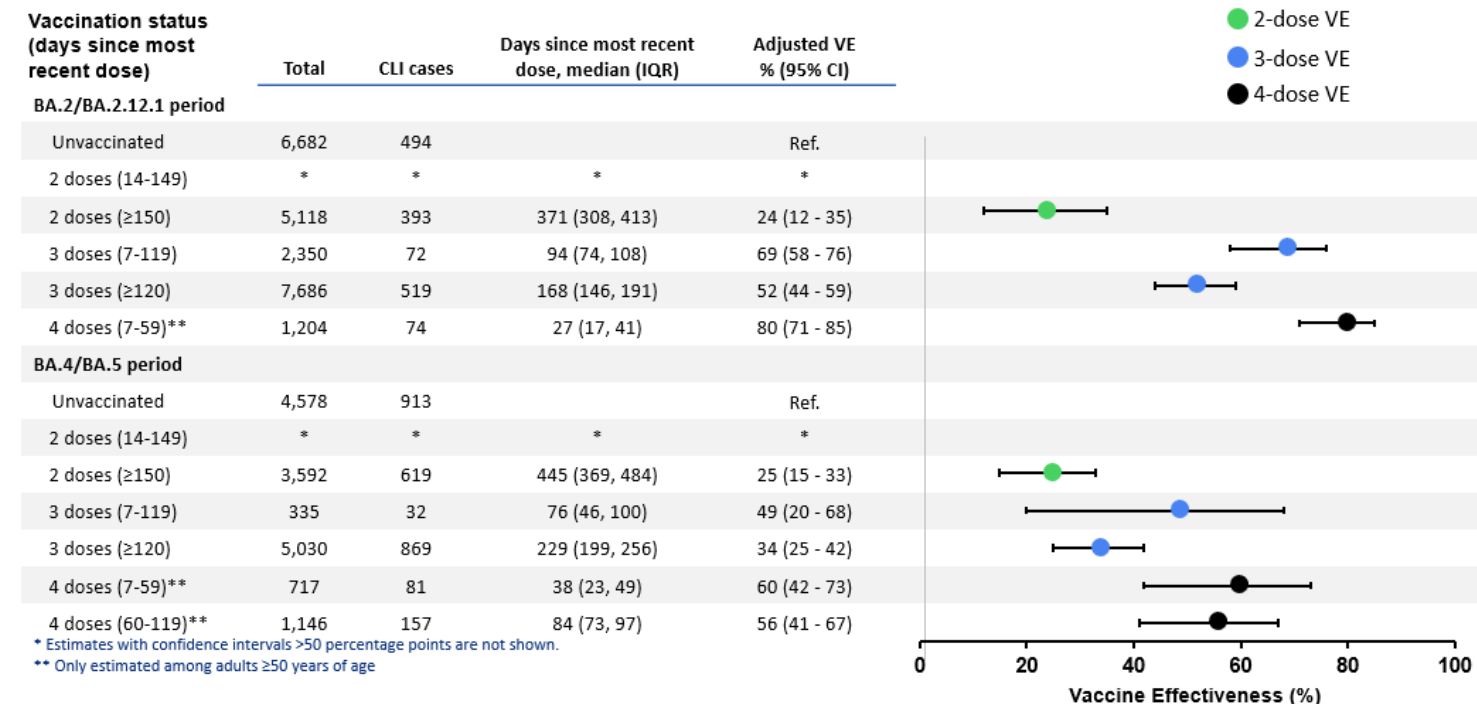
Aug 01, 2020 - Feb 13, 2023



<https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions>

How frequently should people get a COVID-19 vaccine?

VISION: mRNA VE for hospitalizations among immunocompetent adults ≥18 years by number of doses and time since last dose receipt, late-Mar–late-Jul 2022



- With monovalent COVID-19 vaccines, declines in VE noted over time
- Likely impacted by both **time since vaccine dose** and continued **virus evolution**
- Additional vaccine doses restored protection lost over time
- Continue to monitor impact of waning and virus evolution on VE for bivalent vaccines

VE = vaccine effectiveness

BA.2/BA.2.12.1 estimates: Link-Gelles et al. *MMWR*: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm>

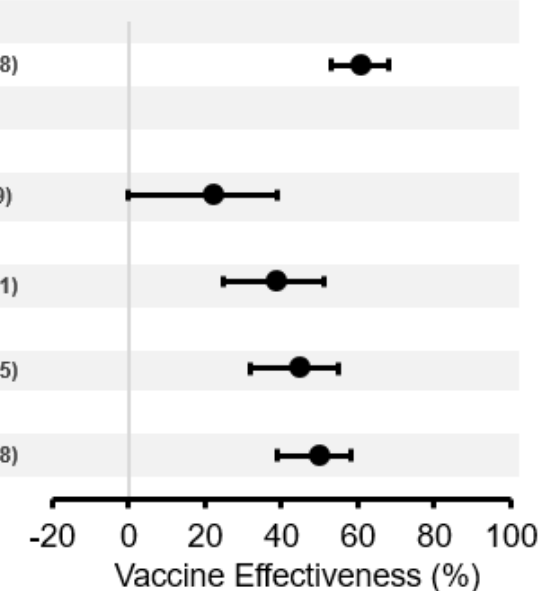
BA.4/BA.5 estimates: Link-Gelles et al. *medRxiv*: <https://www.medrxiv.org/content/10.1101/2022.10.04.22280459v1>. Individuals with prior infections excluded. Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying medical conditions, and propensity to be vaccinated.

How frequently should people get a COVID-19 vaccine?

- Time since last dose impacts COVID-19 vaccine effectiveness
 - Relative VE of bivalent boosters (meaning the **additional benefits** of a bivalent booster) are higher the longer it has been since the last monovalent dose
- Safety is also likely improved with longer time between doses
 - Myocarditis risk appears **lower** with **longer time** between doses

VISION: VE of bivalent COVID-19 boosters against hospitalizations among adults aged ≥18 years – VISION Network, September–December 2022

mRNA Dosage Pattern	Total	SARS-CoV-2-test-positive, no. (%)	Median interval since last dose, days (IQR)	Adjusted VE (95% CI)
Absolute VE				
Unvaccinated (Ref)	7,316	857 (12)	—	Ref
Bivalent booster dose, 7+ days earlier	2,052	150 (7)	33 (19-49)	61 (53-68)
Relative VE				
Only monovalent doses, last dose 2–4 months earlier (Ref)	1,969	156 (8)	117 (95-135)	Ref
Bivalent booster dose, 7+ days earlier	2,052	150 (7)	33 (19-49)	22 (0-39)
Only monovalent doses, last dose 5–7 months earlier (Ref)	2,693	277 (10)	184 (167-208)	Ref
Bivalent booster dose, 7+ days earlier	2,052	150 (7)	33 (19-49)	39 (25-51)
Only monovalent doses, last dose 8–10 months earlier (Ref)	3,402	319 (9)	296 (274-314)	Ref
Bivalent booster dose, 7+ days earlier	2,052	150 (7)	33 (19-49)	45 (32-55)
Only monovalent doses, last dose ≥11 months earlier (Ref)	7,965	890 (11)	446 (366-566)	Ref
Bivalent booster dose, 7+ days earlier	2,052	150 (7)	33 (19-49)	50 (39-58)



VE = vaccine effectiveness

CDC unpublished data. Updated from: Tenforde et al. MMWR December 16, 2022: <https://www.cdc.gov/mmwr/volumes/71/wr/mm715152e1.htm>

How frequently should people get a COVID-19 vaccine?

Summary

- Winter months and immune escape variants have impacted COVID-19 epidemiology
 - This past winter did not see same level of increases in cases/hospitalizations as previous winters
- 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
- 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

Are there populations who still need a primary series?

Unvaccinated young children

- While most adults have completed a primary series, most children ages 6 months – 4 years remain **unvaccinated**
- For most older children, adolescents, and adults, future doses will be additional ‘boost’ after prior infection, prior vaccination, or both
- Young children will continue to age into the vaccine recommendations at 6 months and could be SARS-CoV-2 naive
- Some population of **young children** likely still need a ‘**prime**’ and ‘**boost**’ to optimize immunity

Coverage / Age (years)	<2 years	2–4 years
At least 1-dose	7.6	10.3
Completed primary series	3.7	5.5
Unvaccinated	92.4	89.7

Parental intent to get a COVID-19 vaccine for their child and trusted places for children to receive a COVID-19 vaccine

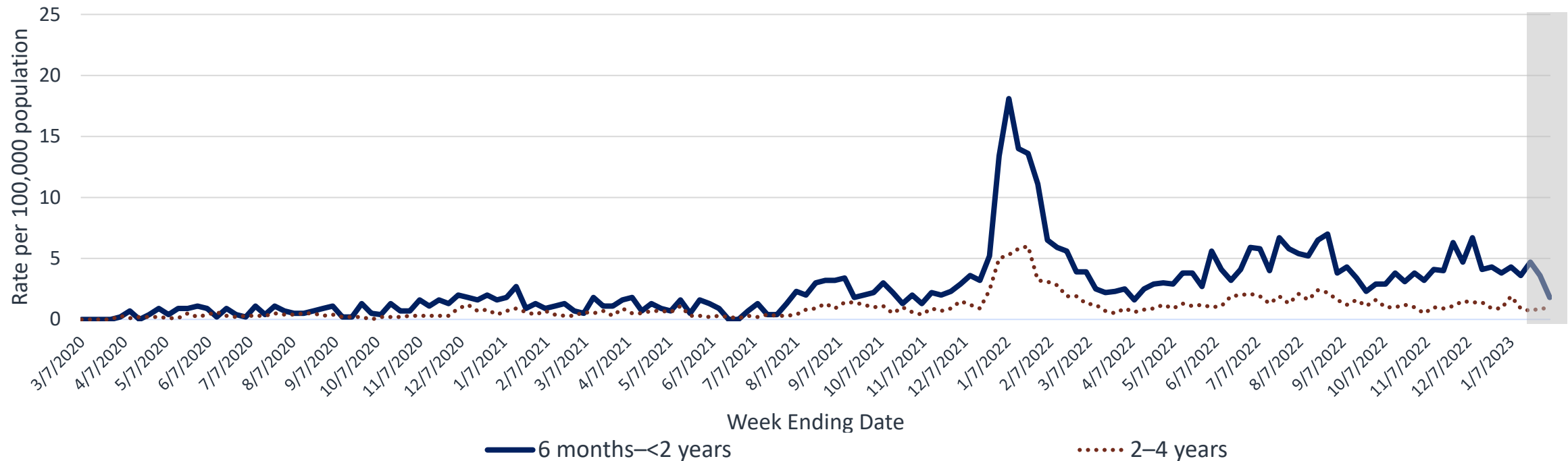
- For parents with an unvaccinated or under-vaccinated child aged 6 – 23 months, **38%** intend to get their child vaccinated in the next month, whereas **39.4%** say they ‘definitely’ or ‘probably’ *will not* vaccinate their child and **23%** are unsure
- Additionally, **38%** of parents of children ages 2 – 4 years say they ‘definitely’ or ‘probably’ *will* get their child vaccinated in the next month, while **43.2%** say they ‘definitely’ or ‘probably’ *will not* and **18.4%** are unsure
- Doctor’s offices and clinics were the most trusted place for parents to have their child receive a COVID-19 vaccine, as reported by **51.1%** of parents of children aged 6 – 23 months and **52.5%** of parents of children aged 2 – 4 years

Are there populations who still need a primary series?

Unvaccinated young children

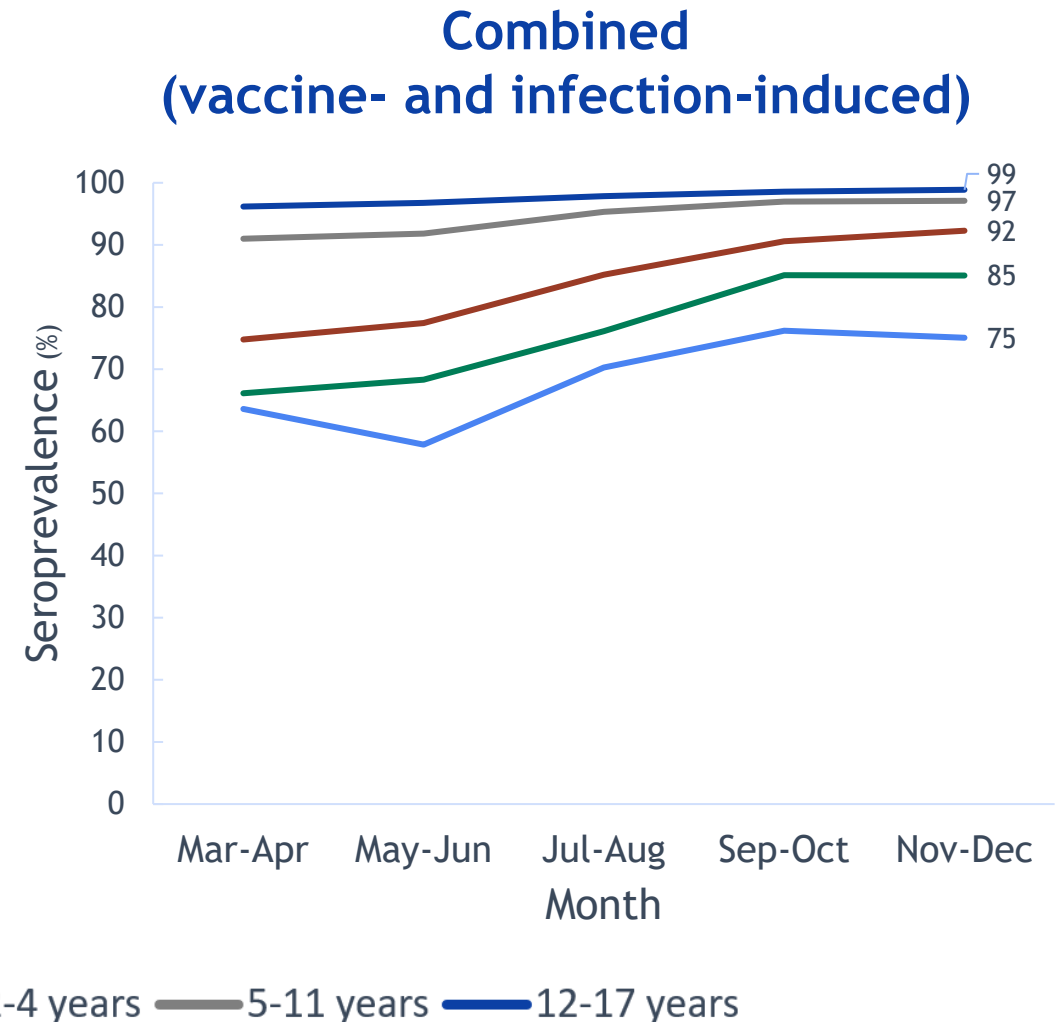
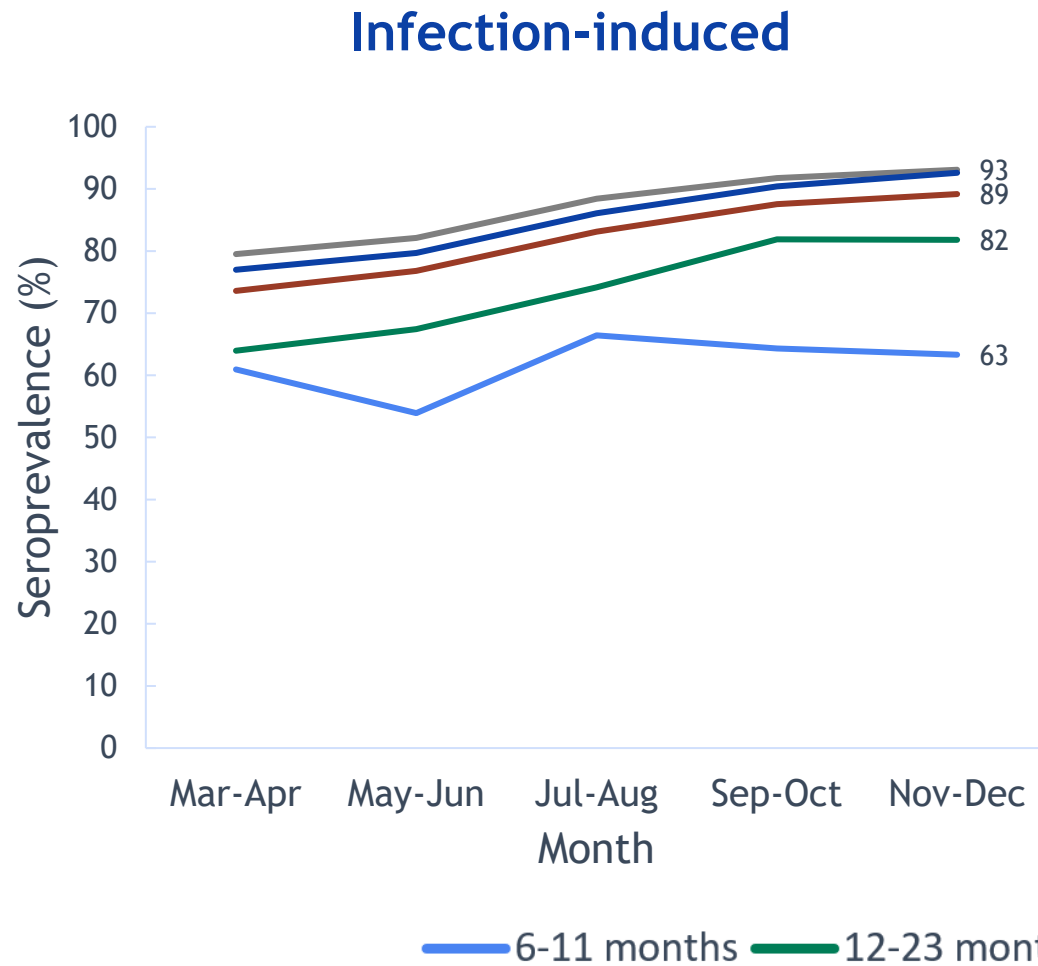
- Pediatric hospitalization rates are higher among children **6 months to <2 years** of age, compared to **children 2–4 years** of age

Weekly Population-Based Rates of COVID-19-Associated Hospitalizations among Children Ages 6 months-4 Years
— COVID-NET, March 2020–February 2023



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

Pediatric SARS-CoV-2 Infection-Induced and Combined (Vaccine- and Infection-Induced) Seroprevalence from U.S. Commercial Laboratories — March–December 2022



Are there populations who still need a primary series?

Summary

- Children ages <2 years have higher COVID-19 hospitalization rates than older children
- Children ages <4 years are less likely to have both prior infection and prior vaccination
- Children have frequent visits to healthcare providers
- The Work Group discussed continued primary series recommendations for young children
- Both ages **6 months-2 years** and ages **6 months-4 years** were discussed without a clear consensus

AAP Schedule of Well-Child Care Visits

Parents know who they should go to when their child is sick. But pediatrician visits are just as important for healthy children.

The *Bright Futures*/American Academy of Pediatrics (AAP) developed a set of comprehensive health guidelines for well-child care, known as the "**periodicity schedule**." It is a schedule of screenings and assessments recommended at each well-child visit from infancy through adolescence.



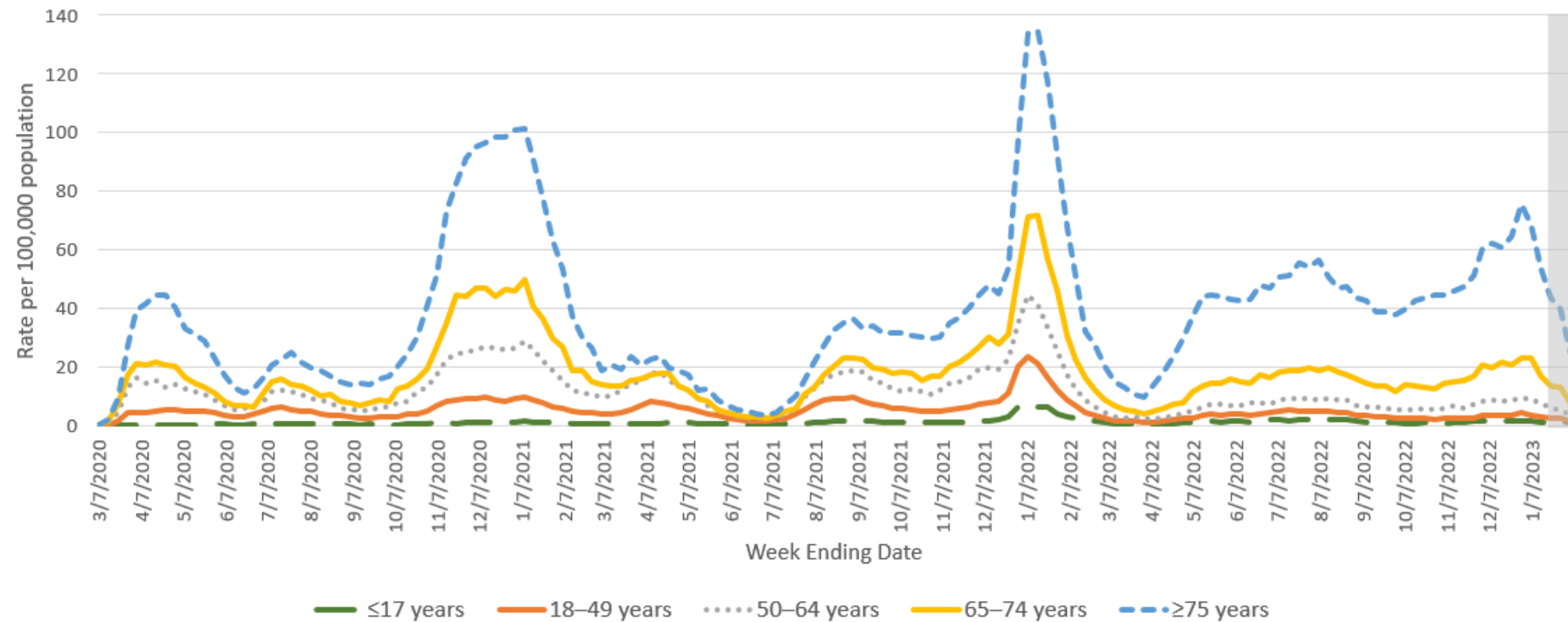
Schedule of well-child visits

- The first week visit (3 to 5 days old)
- 1 month old
- 2 months old
- 4 months old
- 6 months old
- 9 months old
- 12 months old
- 15 months old
- 18 months old
- 2 years old (24 months)
- 2 ½ years old (30 months)
- 3 years old
- 4 years old
- 5 years old

Should older adults be recommended for >1 vaccine annually?

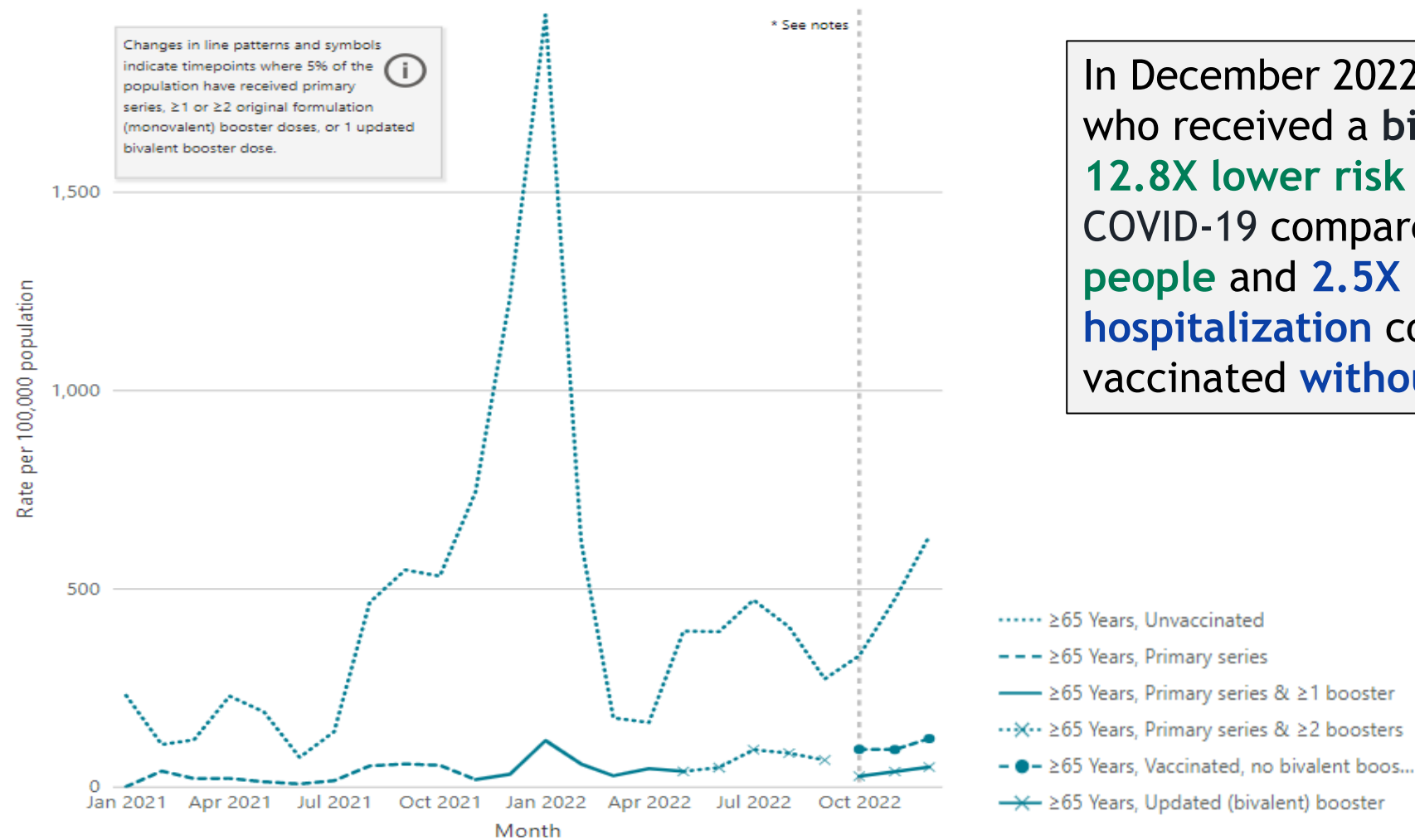
- Hospitalization rates are highest among adults **65–74 years** and **≥75 years of age**

Weekly Population-Based Rates of COVID-19-Associated Hospitalizations among All Ages — COVID-NET, March 2020–February 2023



Age-Adjusted Rates of COVID-19-Associated Hospitalization by Vaccination Status and Receipt of Booster Dose in Adults Ages ≥ 65 Years

COVID-NET, January 2021–December 2022

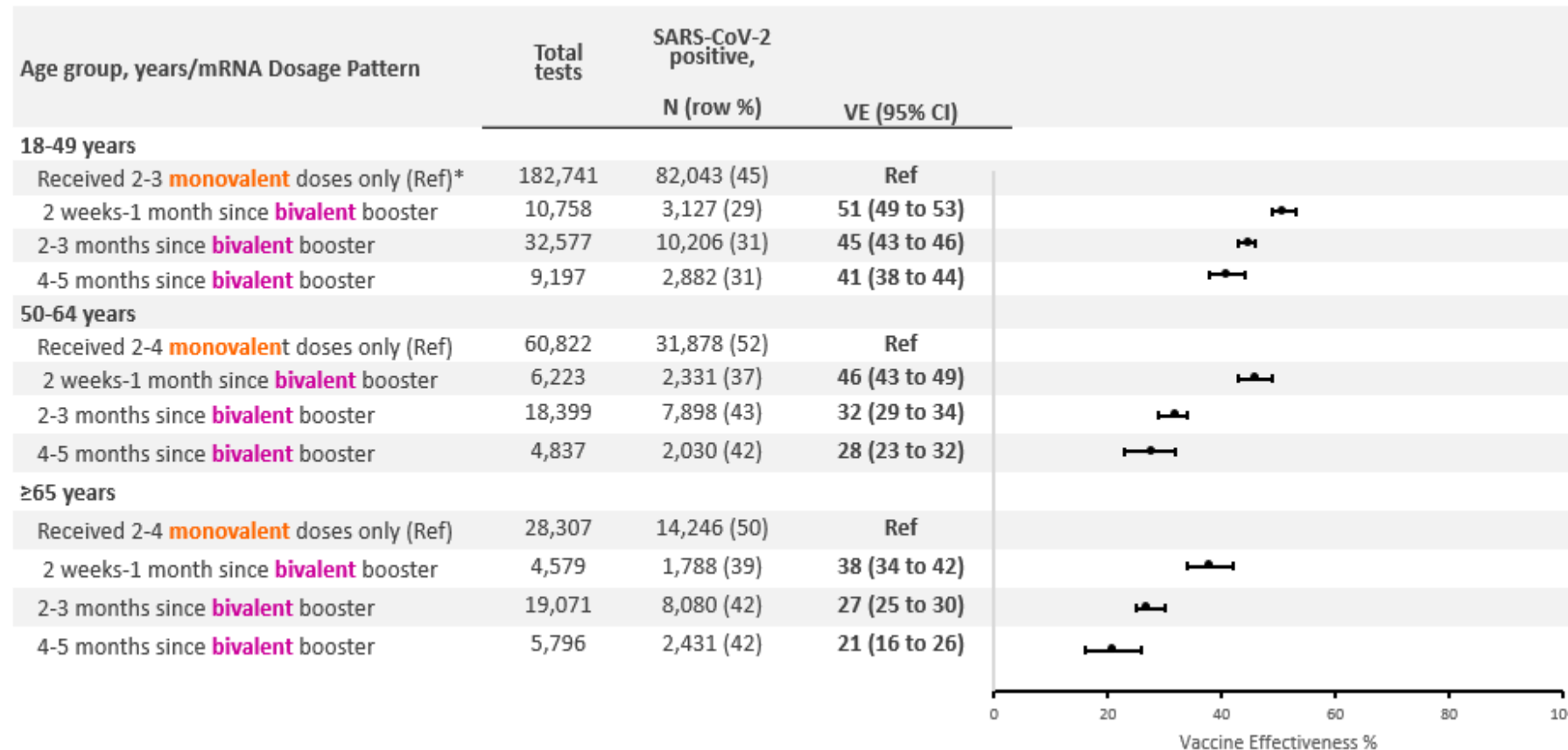


In December 2022, adults ages ≥ 65 years who received a bivalent booster had **12.8X lower risk of hospitalization for COVID-19** compared to **unvaccinated people** and **2.5X lower risk of hospitalization** compared to those vaccinated **without a bivalent booster**

Should older adults be recommended for >1 vaccine annually?

- Immunity and vaccine response is different in older adults
- Patterns of vaccine effectiveness, including waning, may be different in older adults
- Waning for bivalent VE against hospitalization, including among older adults, isn't yet known

ICATT: *Relative VE of bivalent booster against symptomatic infection in adults aged ≥ 18 years, December 1, 2022 - February 13, 2023*



Should older adults be recommended for >1 vaccine annually?

Summary

- Older adults have higher rates of hospitalization than younger adults
- Rates of vaccination among older adults who have received a bivalent COVID-19 vaccine booster dose **remain low**
- The Work Group emphasized the importance of older adults being **up to date** on current recommendations, including receiving a bivalent booster
- The Work Group discussed more frequent COVID-19 vaccine doses for older adults, and at this time felt the data were **insufficient** to determine a conclusion
- Recommendations can be updated based on data in older adults including:
 - Hospitalization rates of older adults who have received a bivalent booster
 - Bivalent VE and patterns of waning for older adults
 - SARS-CoV-2 virus evolution and possibility of future immune escape variants

Should people with immunocompromise be recommended for >1 vaccine annually?

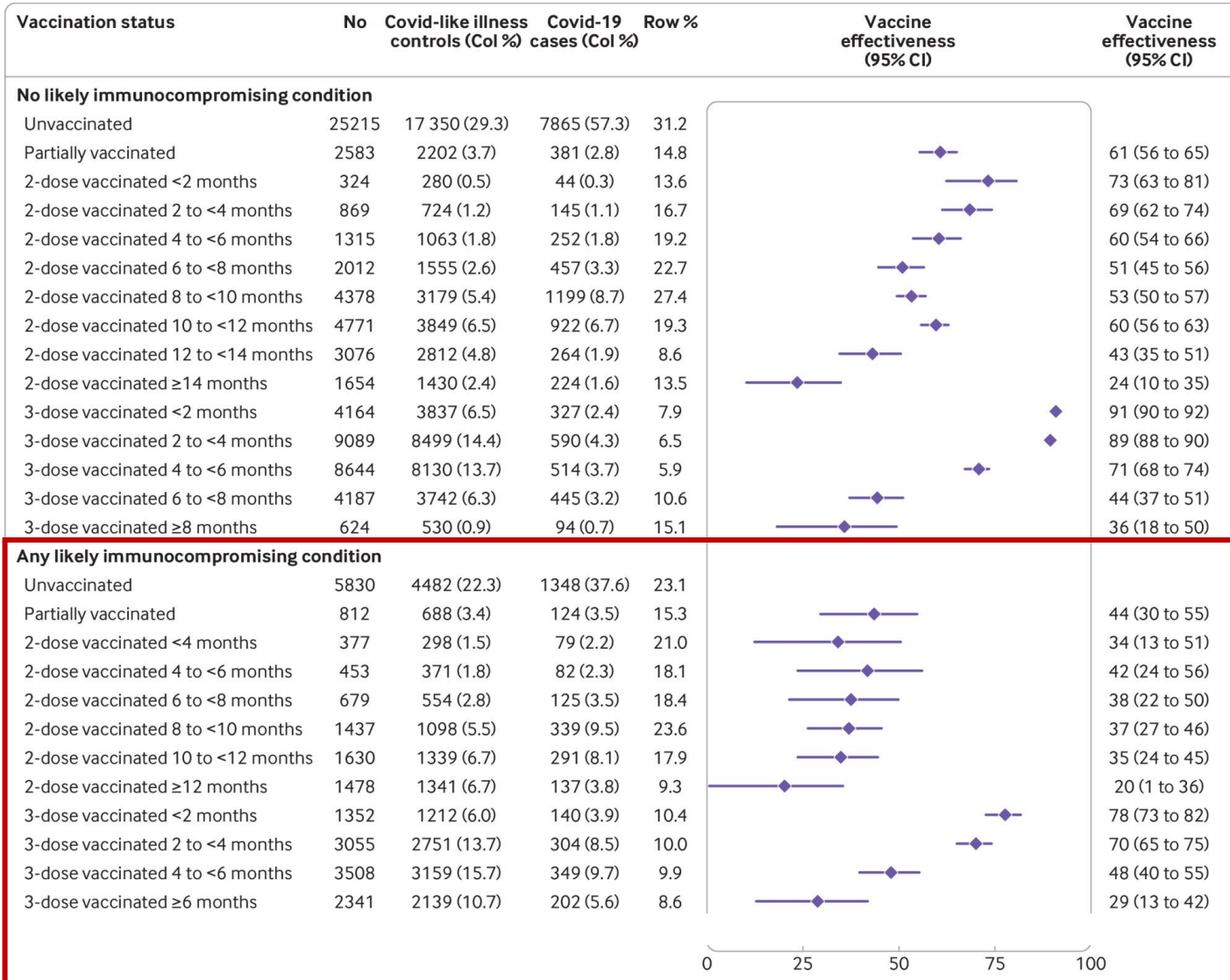
- Numerous studies have demonstrated that mRNA COVID-19 vaccine effectiveness among immunocompromised persons is **lower** than that of immunocompetent persons, including within the period of Omicron predominance
- This has been demonstrated across a range of immunocompromising conditions, and is particularly notable for organ or stem cell transplant recipients
- Among people with immunocompromise, recommendations prior to the bivalent booster allowed for up to 5 monovalent doses of COVID-19 vaccine
- Vaccine effectiveness studies are not yet sufficiently powered to evaluate effectiveness of the bivalent booster among people with immunocompromise

Britton A, Embi PJ, Levy ME, et al. Effectiveness of COVID-19 mRNA Vaccines Against COVID-19–Associated Hospitalizations Among Immunocompromised Adults During SARS-CoV-2 Omicron Predominance — VISION Network, 10 States, December 2021—August 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:1335–1342.

Embi PJ, Levy ME, and Patel P, et al. Effectiveness of COVID-19 Vaccines at Preventing Emergency Department or Urgent Care Encounters and Hospitalizations Among Immunocompromised Adults: an Observational Study of Real-World Data Across 10 US States from August—December 2021. Preprint. [*Effectiveness of COVID-19 Vaccines at Preventing Emergency Department or Urgent Care Encounters and Hospitalizations Among Immunocompromised Adults: An Observational Study of Real-World Data Across 10 US States from August-December 2021 \(medrxiv.org\)](#)

Ferdinands J M, Rao S, Dixon B E, Mitchell P K, DeSilva M B, Irving S A et al. Waning of vaccine effectiveness against moderate and severe covid-19 among adults in the US from the VISION network: test negative, case-control study *BMJ* 2022; 379 :e072141 doi:10.1136/bmj-2022-072141

Should people with immunocompromise be recommended for >1 vaccine annually?



- VE among immunocompromised persons is **lower** than that of immunocompetent persons at comparable time points after dose 2 and dose 3
- VE wanes in both immunocompetent and immunocompromised persons

VISION: mRNA COVID-19 VE for hospitalizations among immunocompetent versus immunocompromised adults during Omicron predominance (mid-Dec. 2021—Jul. 2022)

Figure: Ferdinands J M, Rao S, Dixon B E, Mitchell P K, DeSilva M B, Irving S A et al. Waning of vaccine effectiveness against moderate and severe covid-19 among adults in the US from the VISION network: test negative, case-control study *BMJ* 2022

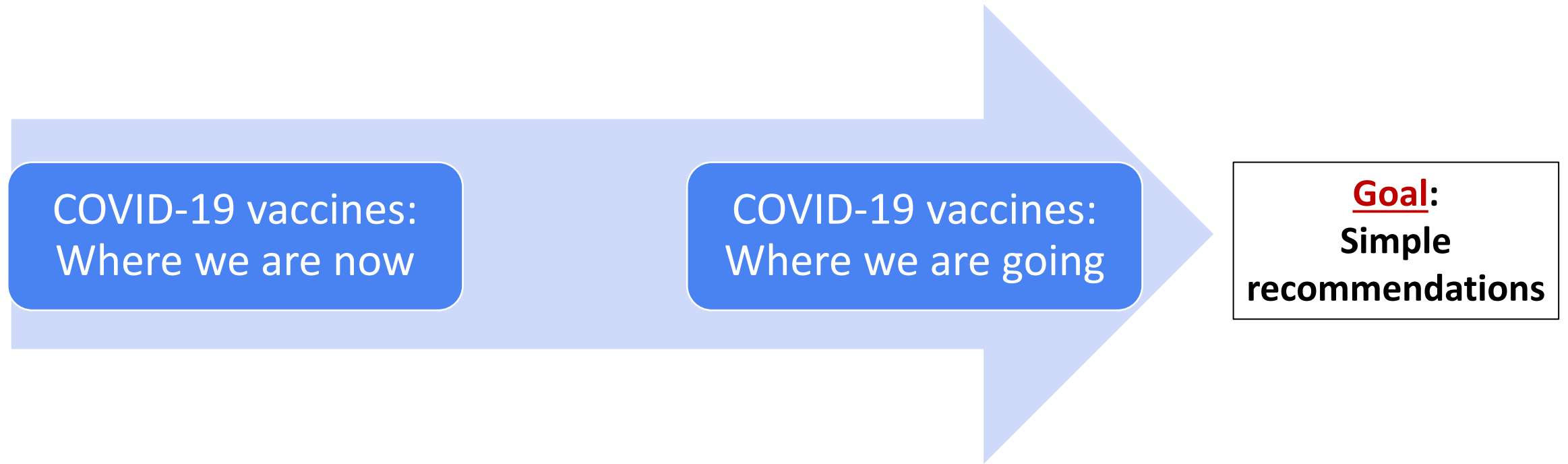
Should people with immunocompromise be recommended for >1 vaccine annually?

Summary

- Immunocompromised adults can have less robust immune response to COVID-19 vaccines
- Not currently any authorized prophylactic monoclonal antibody products for populations at highest risk of COVID-19
- The Work Group discussed more frequent COVID-19 vaccine doses for people with immunocompromise, and at this time felt the data were insufficient to determine a conclusion
- The Work Group acknowledged this population may continue to be more vulnerable to severe COVID-19 and likely needs **flexibility** with COVID-19 vaccine recommendations

Considerations for future planning

COVID-19 vaccines



Considerations for future planning

COVID-19 vaccines

- COVID-19 vaccines continue to be the **most effective tool** we have to prevent **serious illness, hospitalization and death from COVID-19**
- **Goal** of COVID-19 vaccine program continues to be **prevention of severe disease**
 - Prevention of post-COVID conditions, increased confidence in social interactions important as well
- Benefits of additional COVID-19 vaccine booster doses vary by **age, time since last dose**, and **COVID-19 incidence**
- A simplified, annual recommendation could help reduce vaccine and message fatigue
- A COVID-19 vaccine framework that is similar to a well understood influenza vaccine framework could be easy for COVID-19 vaccine providers to implement, and for the public to understand

Work Group interpretation

Considerations for future planning

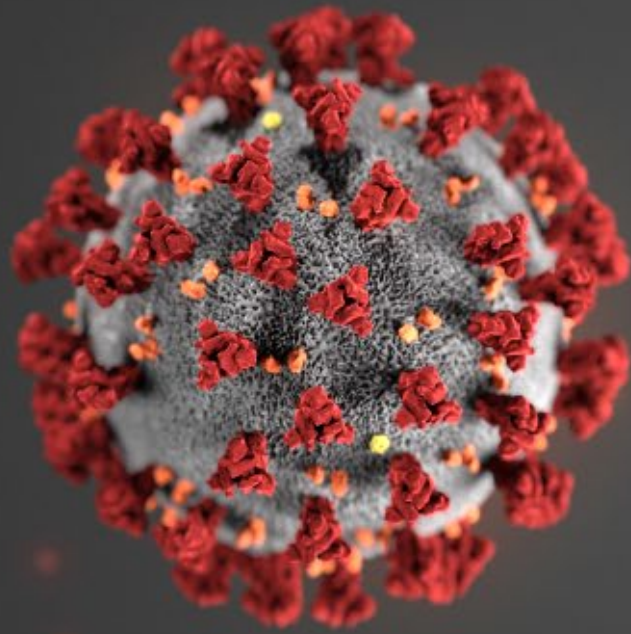
- **Simple recommendations** are easier to communicate, which may improve uptake
 - The Work Group was very supportive of simplified recommendations and planning for future COVID-19 vaccines, which could include updated COVID-19 vaccines
- **Uncertainties remain** for ideal timing and populations for future boosters, especially if new immune escape variants develop
- The Work Group was **supportive** of a fall/annual COVID-19 vaccine program, with flexibility to adjust based on new data, especially for populations at high risk
- The Work Group will continue to **review data** to inform future deliberations:
 - Vaccine effectiveness of bivalent COVID-19 vaccines over time
 - Safety data of bivalent COVID-19 vaccines
 - Cost effectiveness analyses
 - COVID-19 epidemiology, including hospitalization rates among vaccinated and boosted persons
 - SARS-CoV-2 genomic surveillance and virus evolution
 - Data from vaccine manufacturers

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- National Center for Immunization and Respiratory Diseases

Question for ACIP

- Discussions about future COVID-19 vaccine recommendations are pre-decisional and intended to inform planning and additional analyses.
- What are ACIP's thoughts on a **simplified framework** for future COVID-19 vaccine recommendations?
 - What does ACIP think about **children** who may still need a **primary series**?
 - What does ACIP think about future recommendations for **older adults**?
 - What does ACIP think about future recommendations for **people with immunocompromising conditions**?



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.

