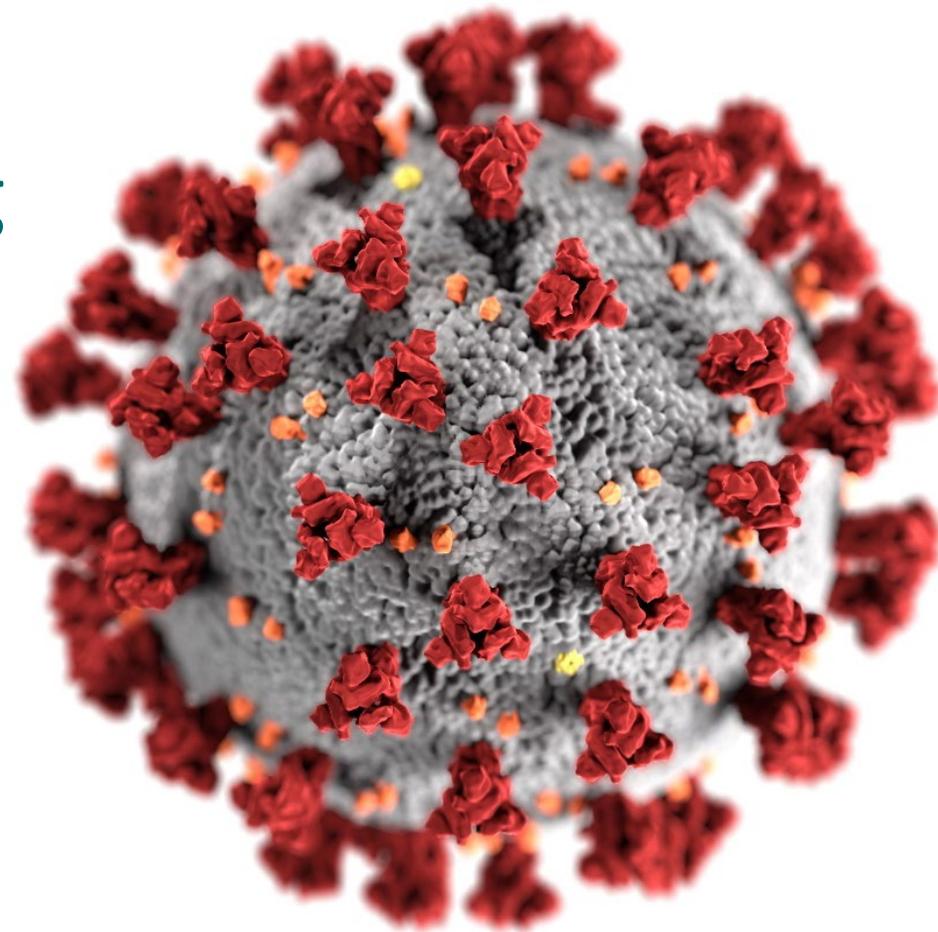


COVID-19 Vaccine: Considerations for Future Planning

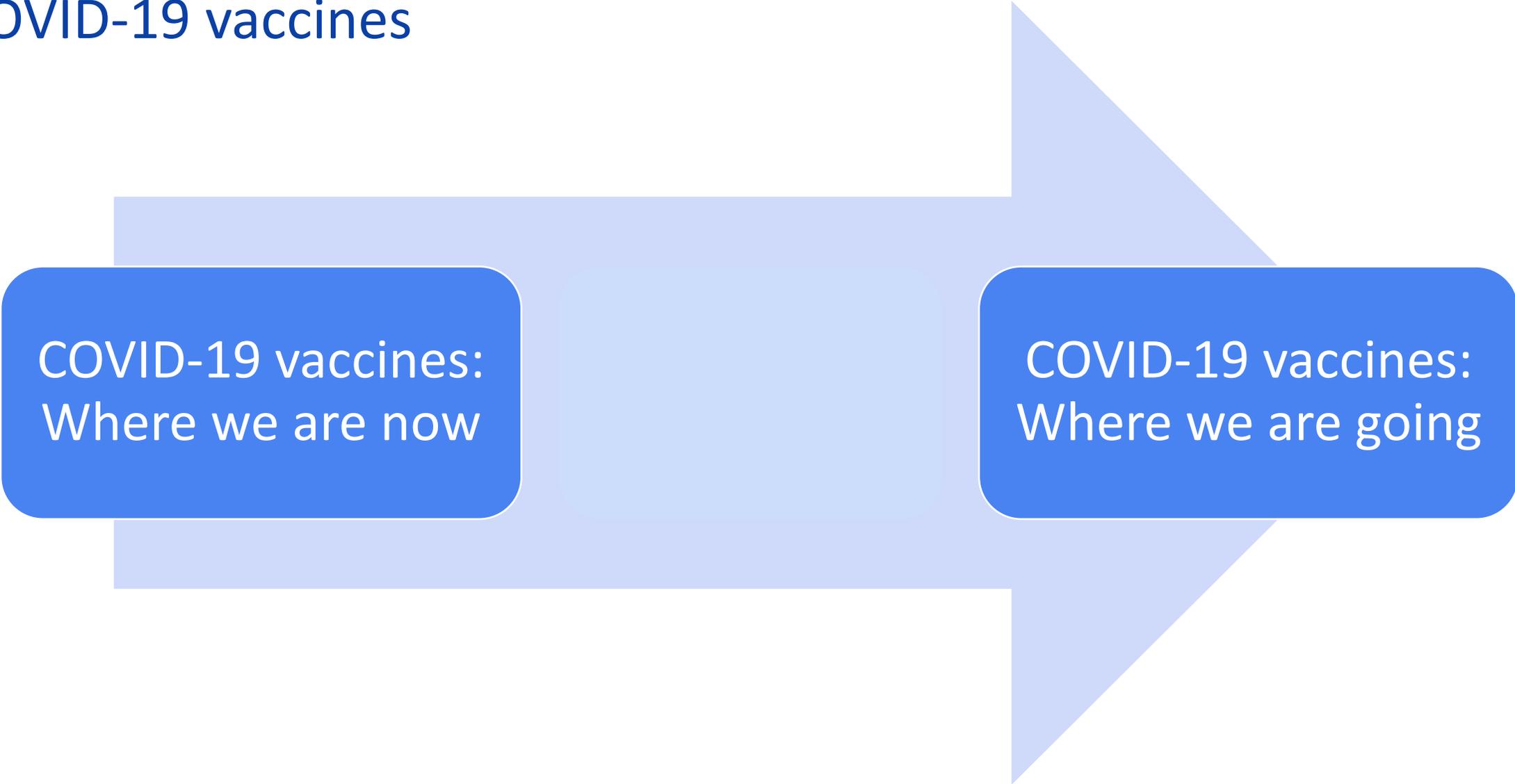
Sara Oliver, MD, MSPH
ACIP Meeting
February 24, 2023



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**

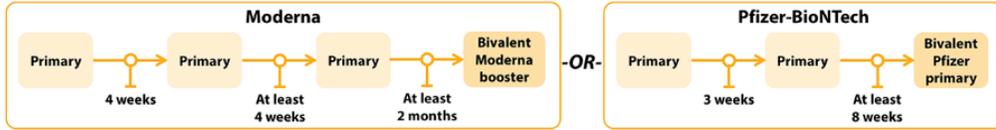
How we get there:

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

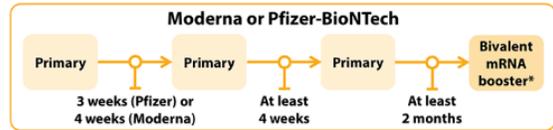
People ages 6 months through 4 years



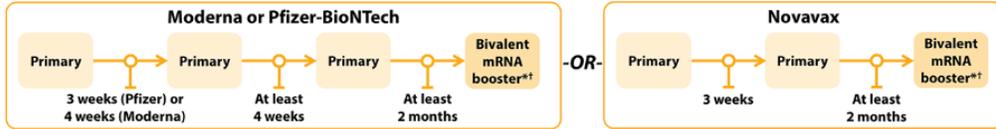
People age 5 years



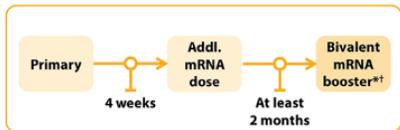
People ages 6 through 11 years



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

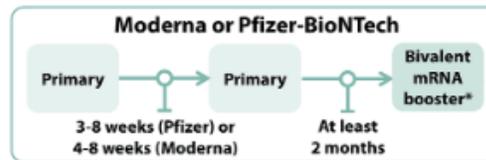
People ages 6 months through 4 years



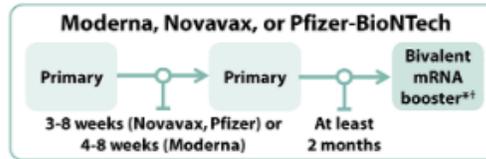
People age 5 years



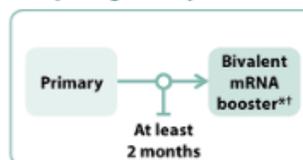
People ages 6 through 11 years



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 | —† | —† |

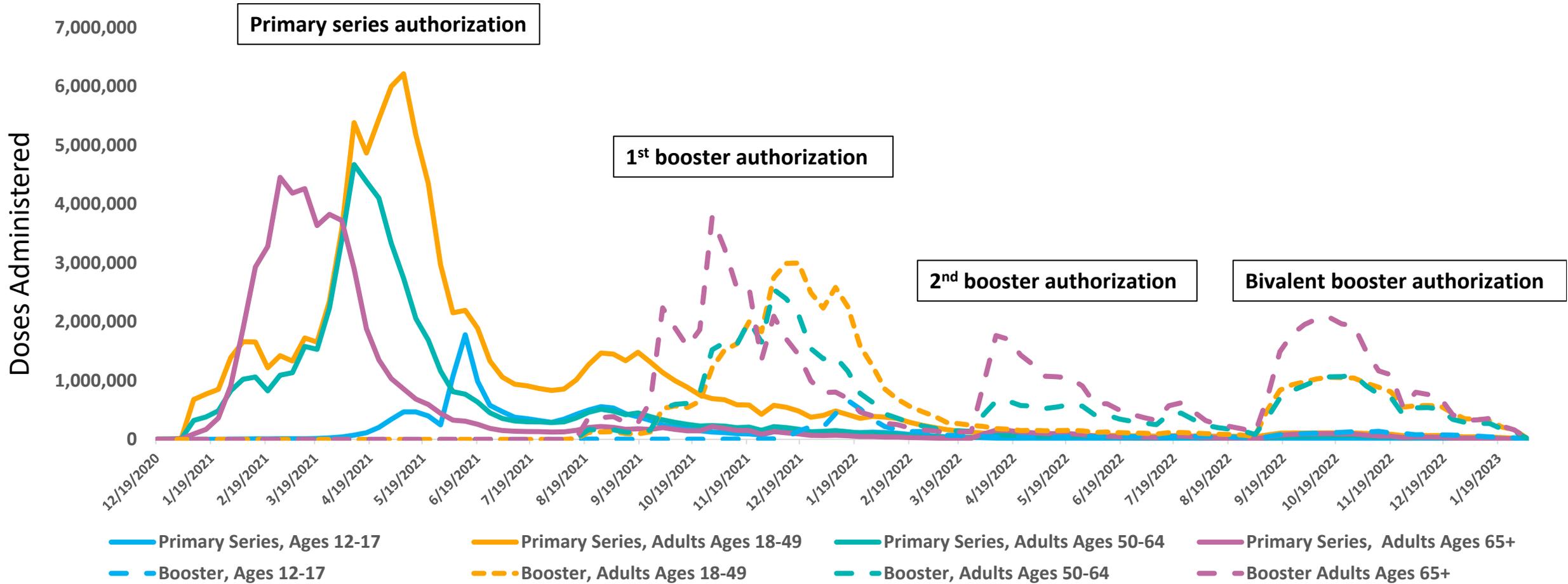
*Monovalent booster dose coverage as of August 26, 2022

** 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



Source: IZ Data Lake

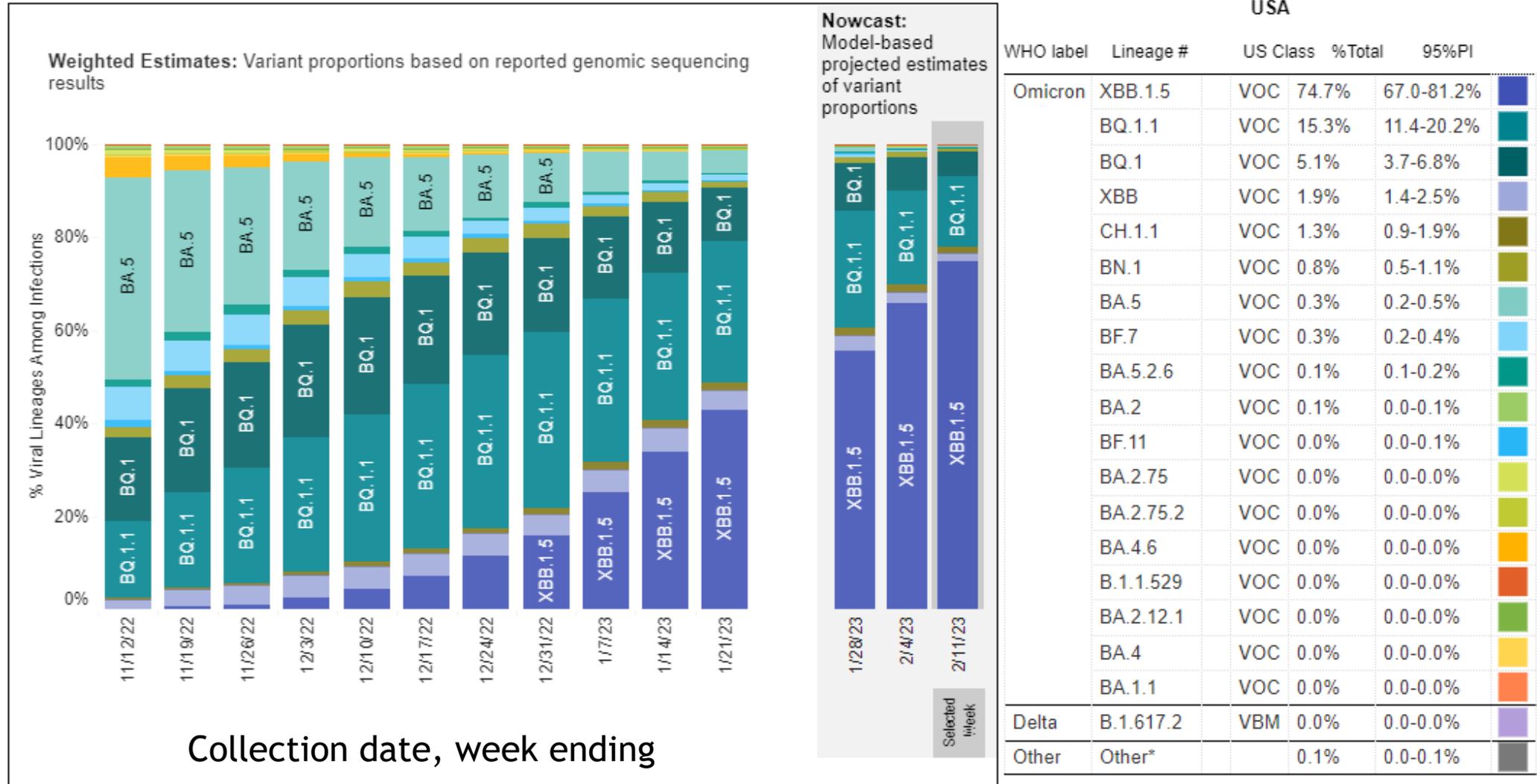
COVID-19 message fatigue challenges vaccine uptake

- 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 \(cdc.gov\)](#)

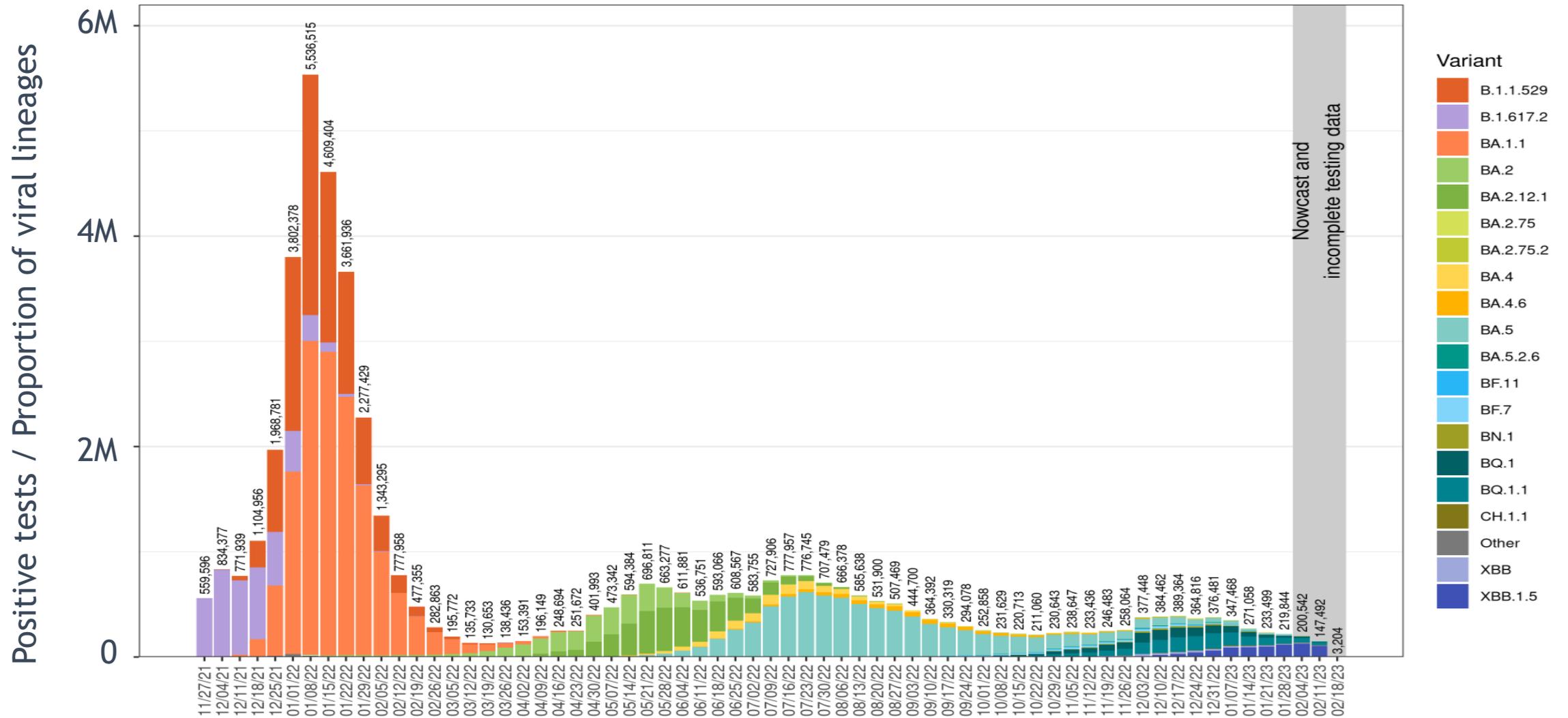
Trends in weighted variant proportion estimates & Nowcast

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



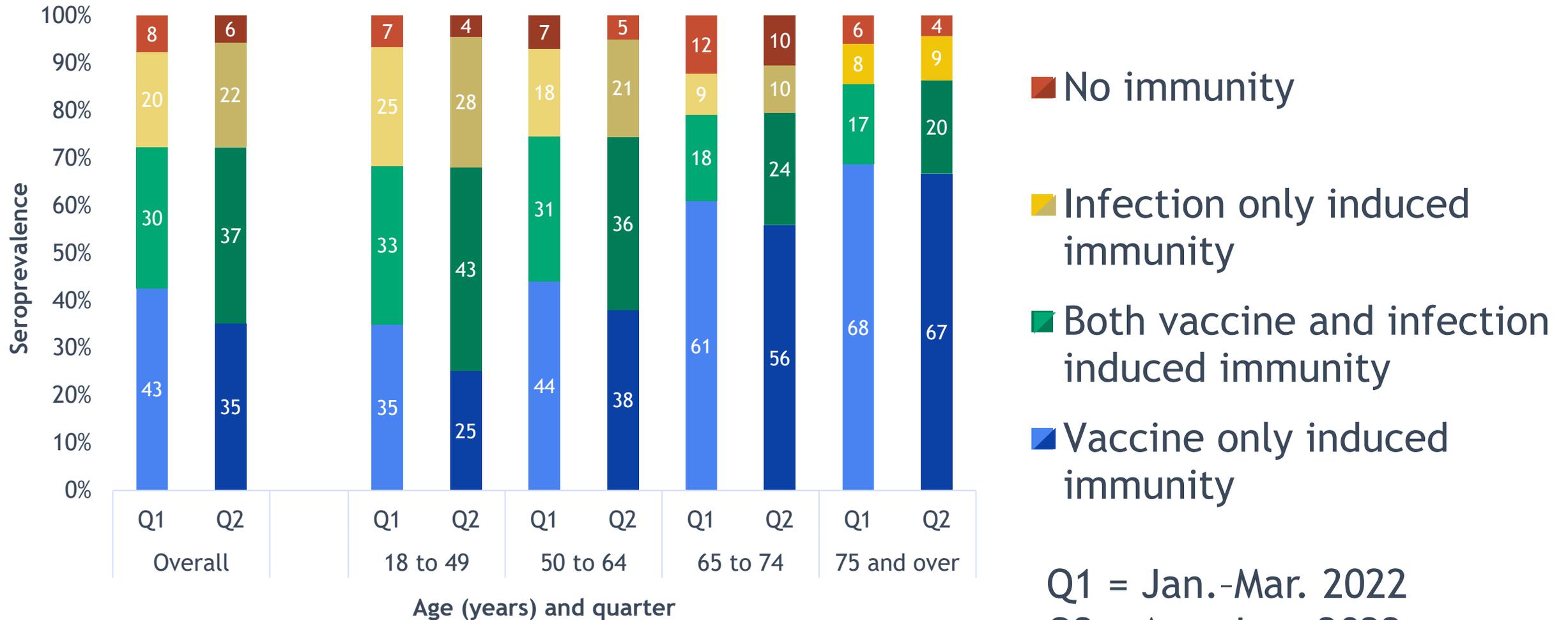
Estimated Number of Reported COVID-19 Cases by Variant

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

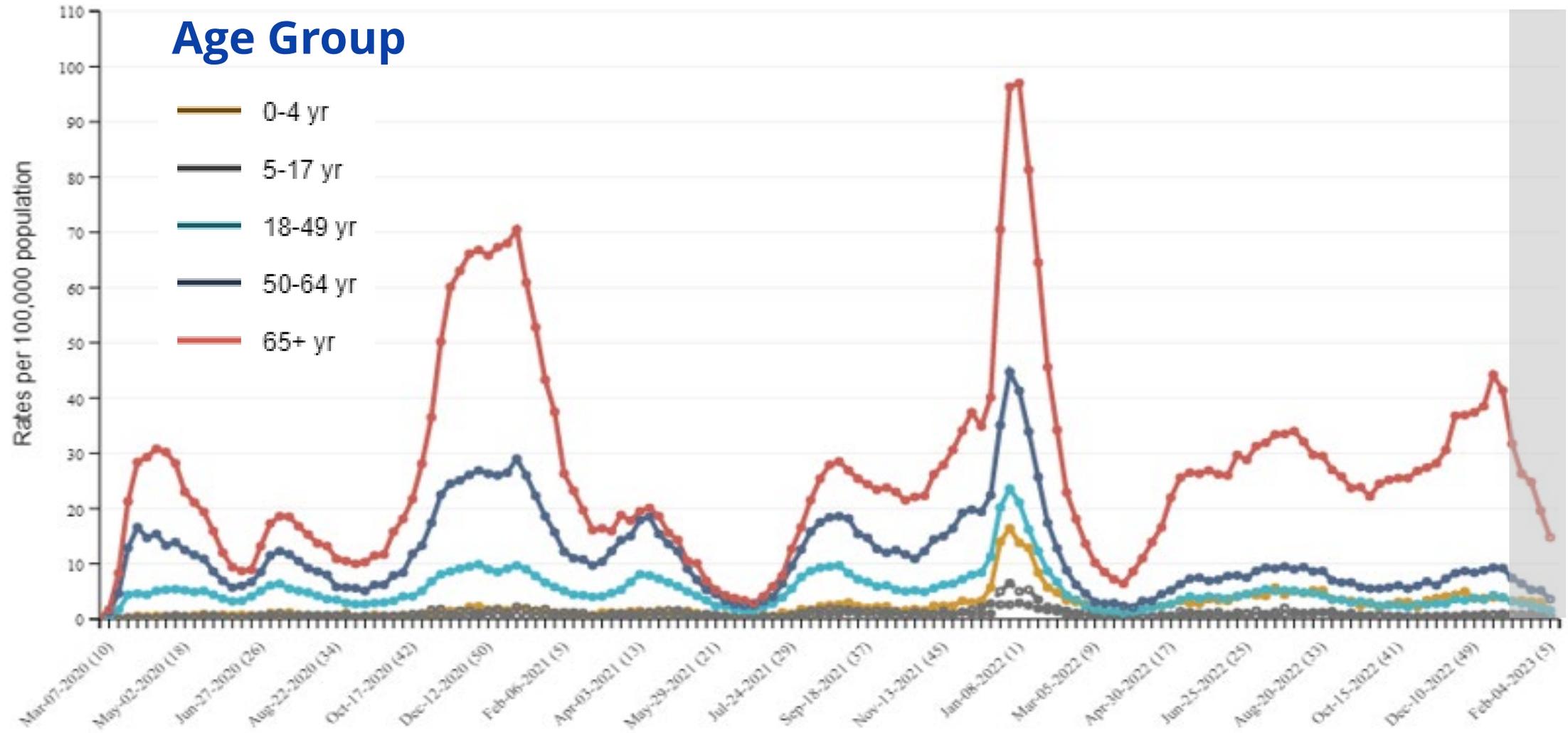


CDC COVID-19 Lab Coordinating Unit Strain Surveillance and Emerging Variant Group. Data sources: <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> and https://covid.cdc.gov/covid-data-tracker/#trends_newtestresultsreported_7daytestingpositive_00

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

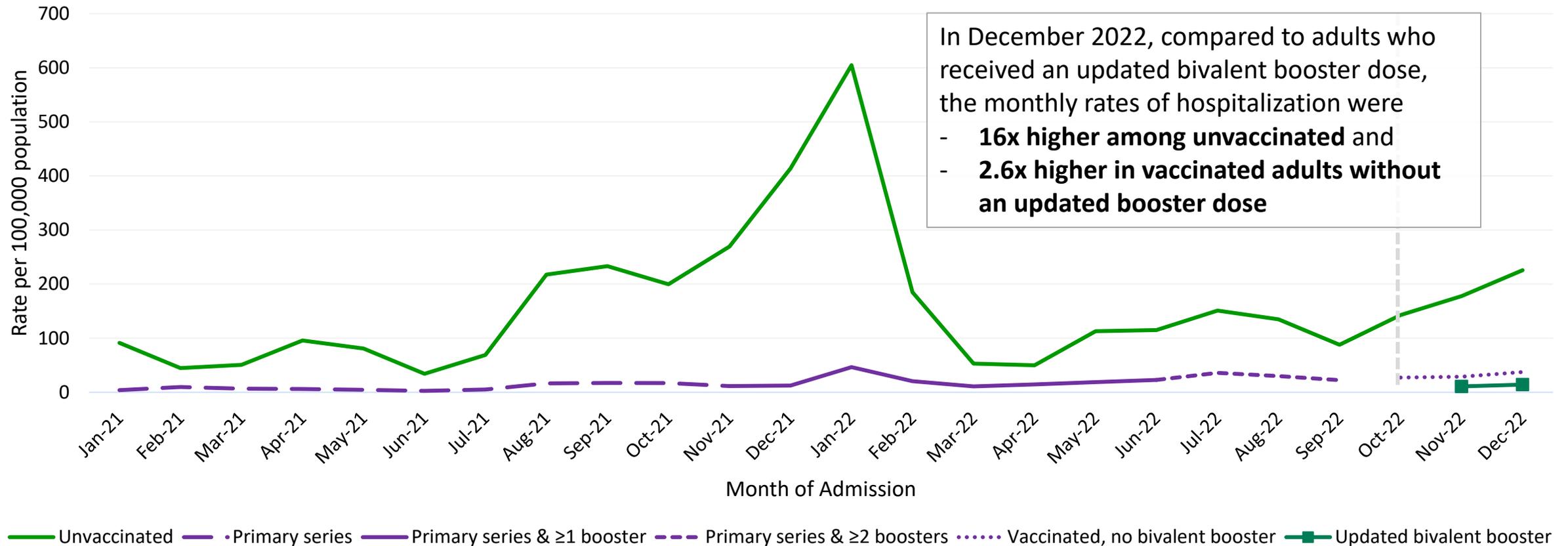


Weekly population-based rates of COVID-19-associated hospitalizations by age group— COVID-NET, March 2020–February 2023



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:

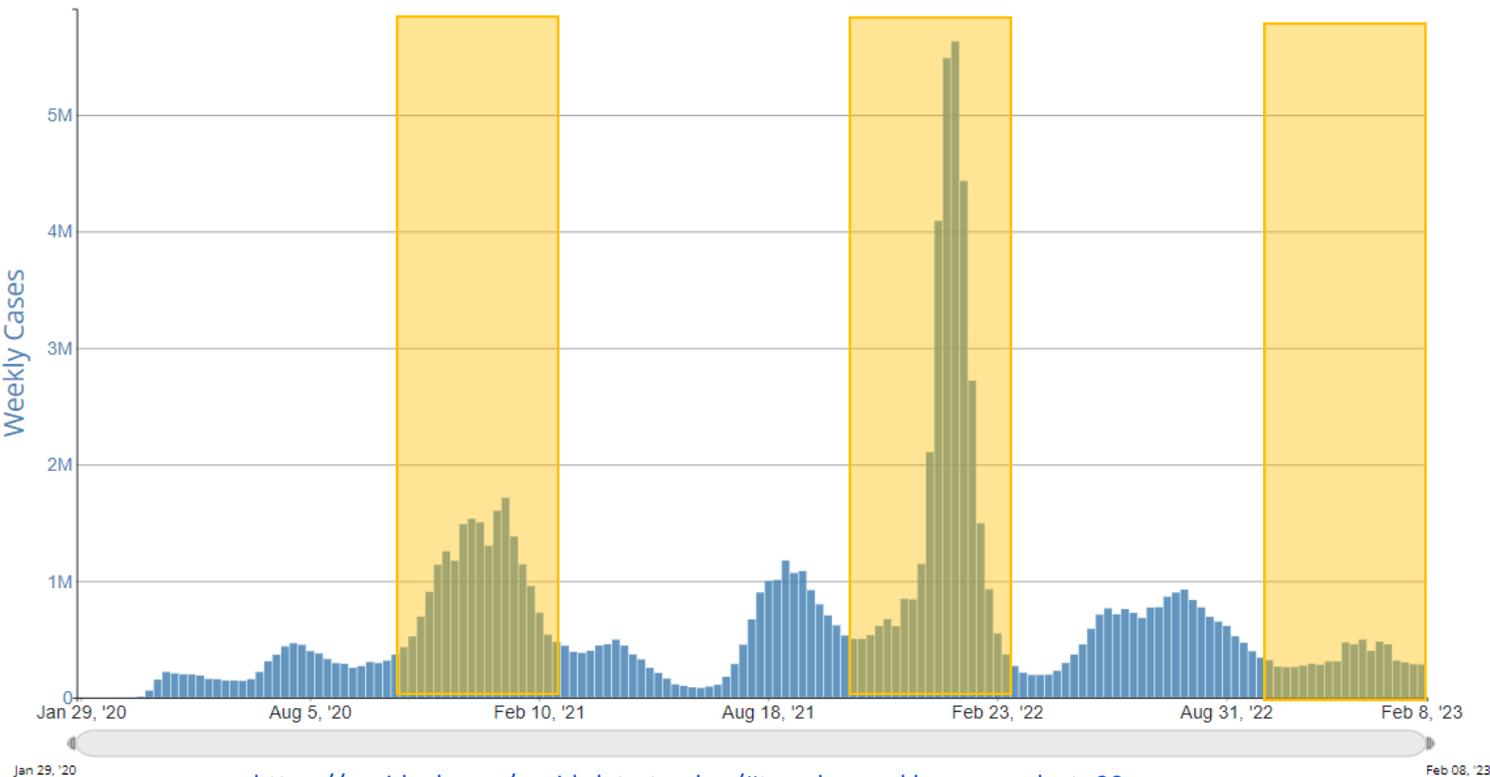
How frequently should people get a COVID-19 vaccine?
Are there groups/populations who should have >1 vaccine per year?

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

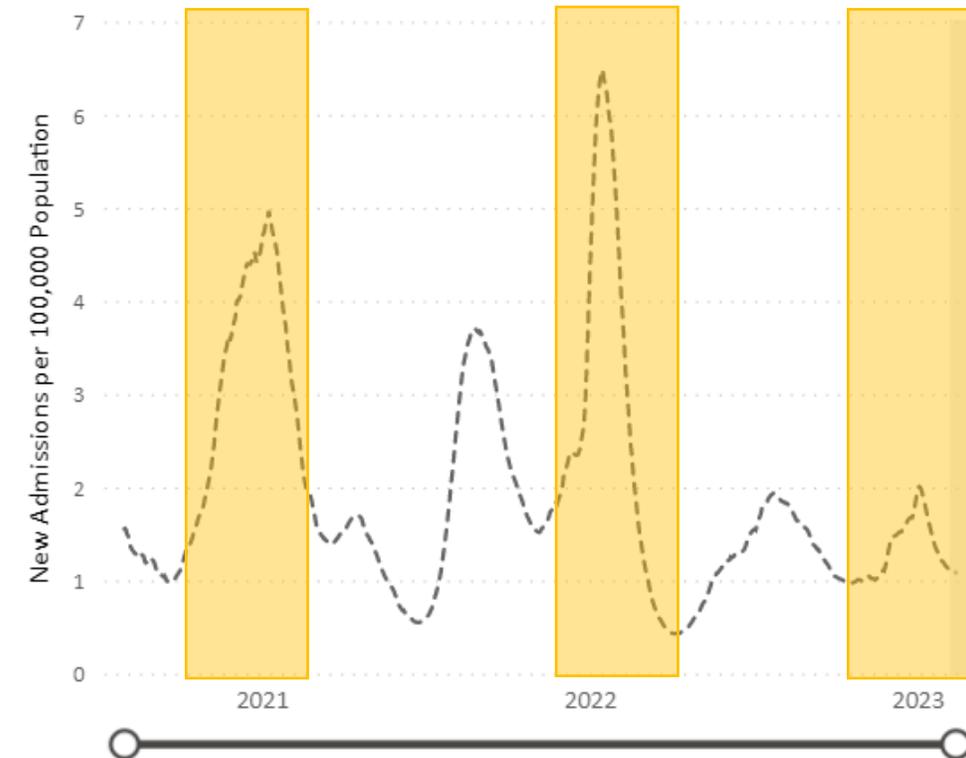


<https://covid.cdc.gov/covid-data-tracker/#trends weeklycases select 00>

Admissions from October 2021 – February 2023 highlighted

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

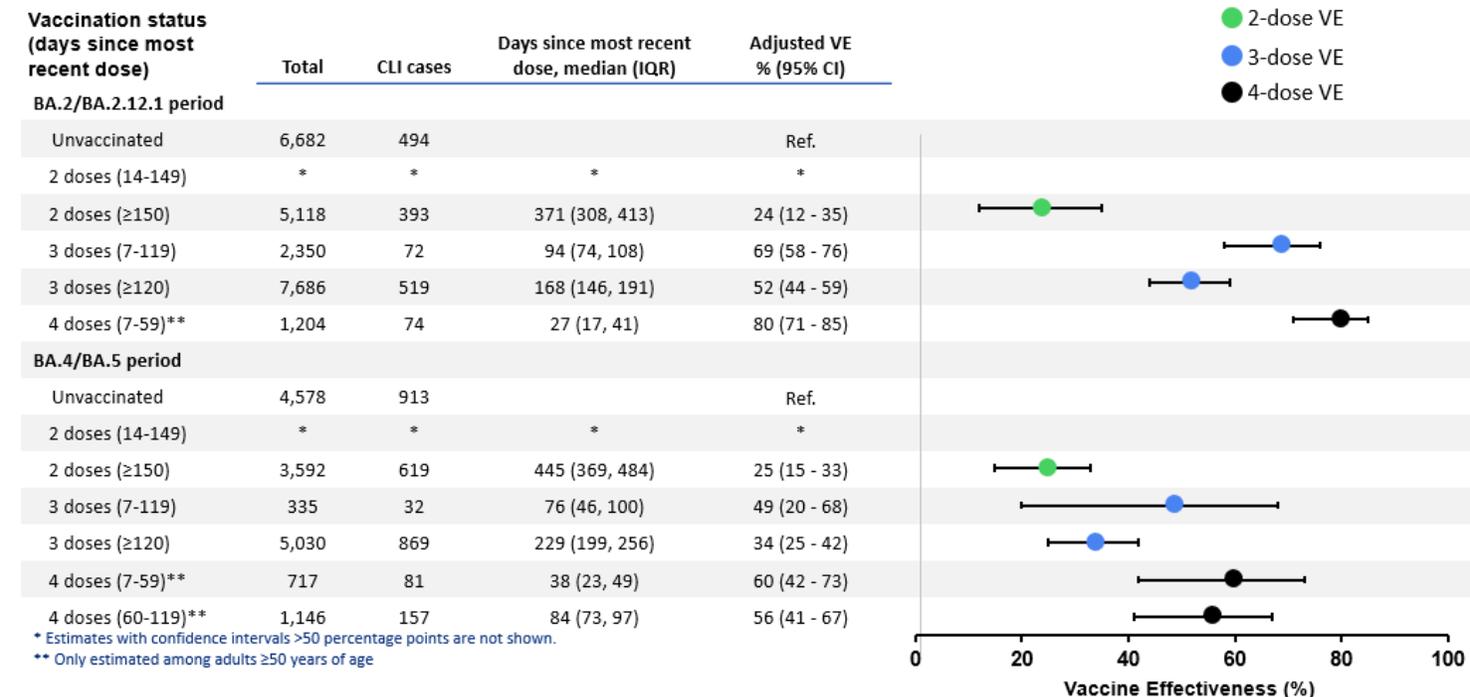
Aug 01, 2020 - Feb 13, 2023



<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>

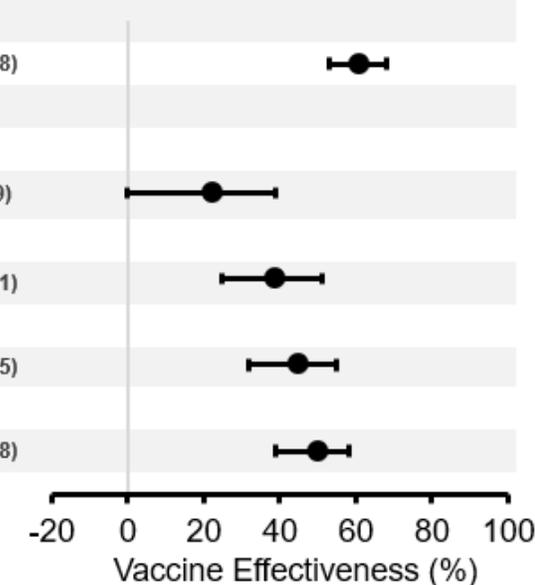
BA.4/BA.5 estimates: Link-Gelles et al. *medRxiv*: <https://www.medrxiv.org/content/10.1101/2022.10.04.22280459v1>. Individuals with prior infections excluded. Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying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

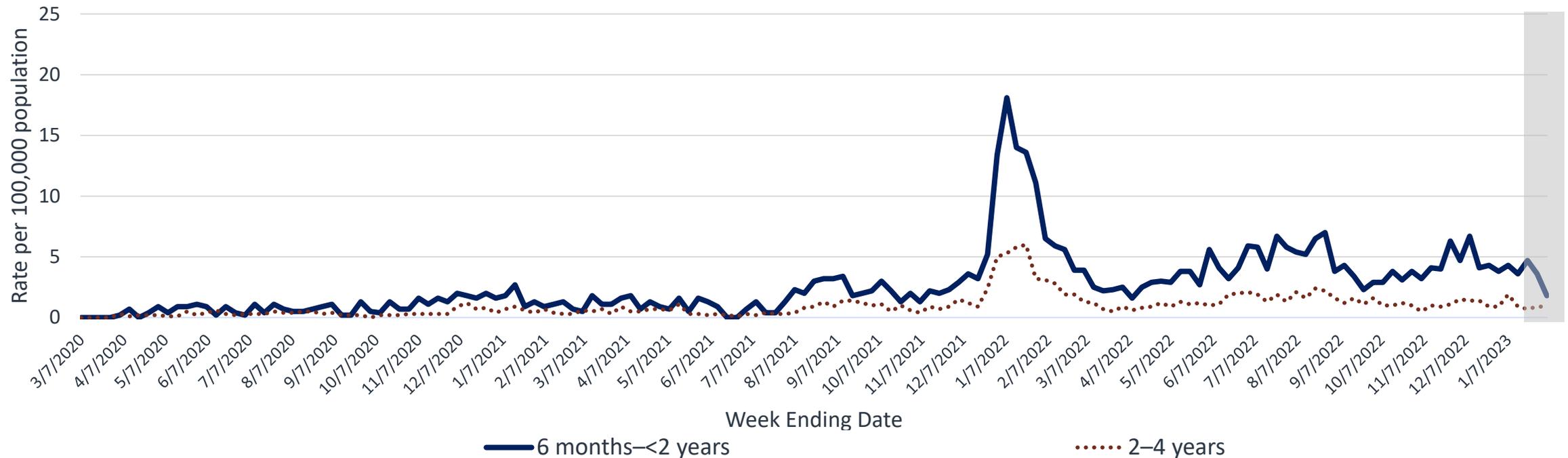
- For parents with an unvaccinated or under-vaccinated child aged 6 – 23 months, **38%** intend to get their child vaccinated in the next month, whereas **39.4%** say they ‘definitely’ or ‘probably’ *will not* vaccinate their child and **23%** are unsure
- Additionally, **38%** of parents of children 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

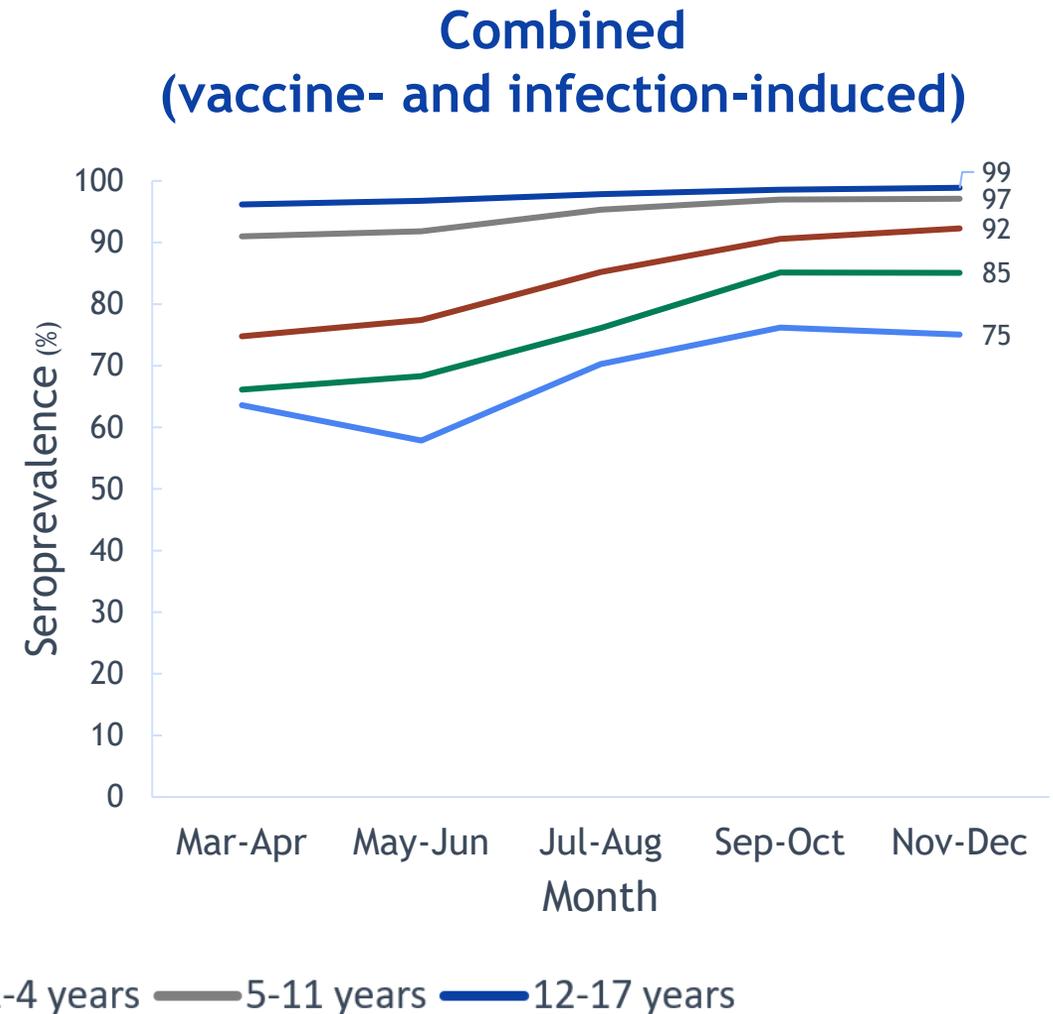
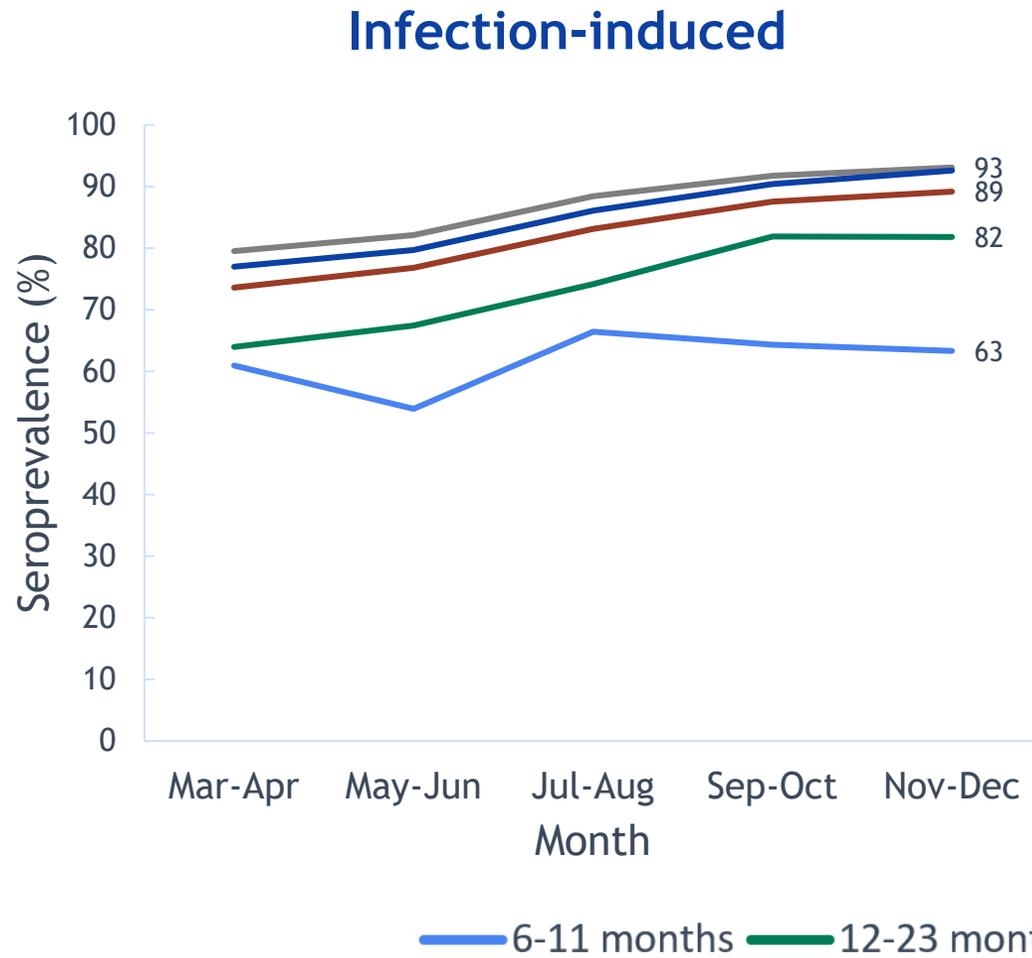
- Pediatric hospitalization rates are higher among children **6 months to <2 years** of age, compared to **children 2–4 years** of age

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.



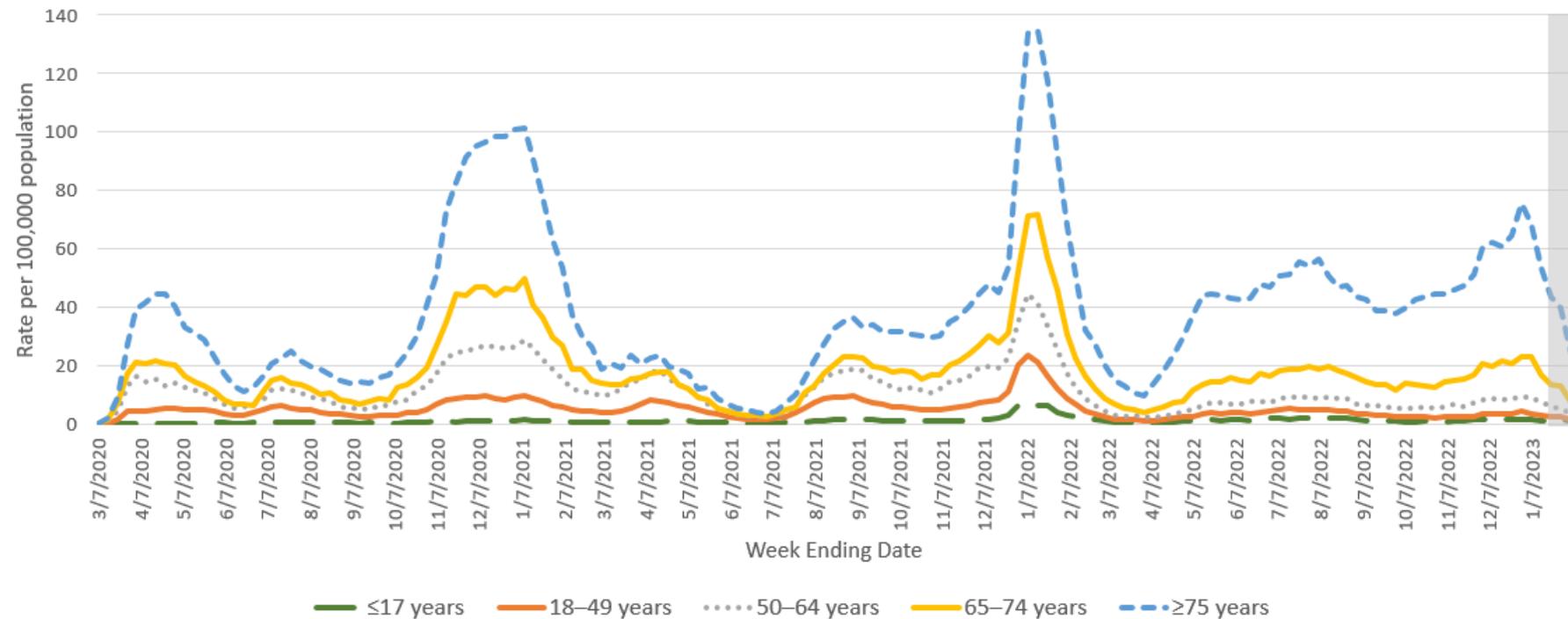
Schedule of well-child visits

- 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?

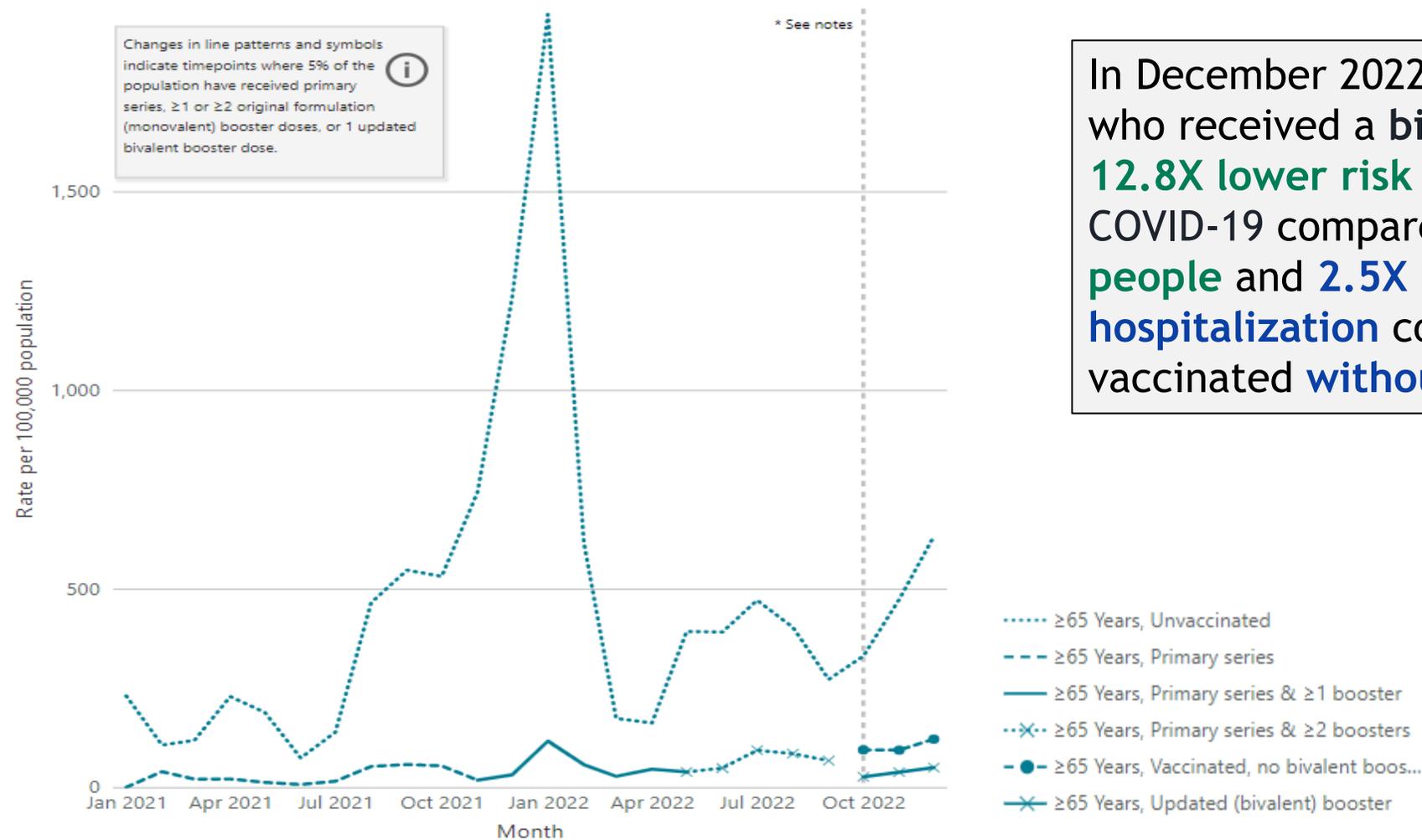
- Hospitalization rates are highest among adults **65–74 years** and **≥75 years of age**

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

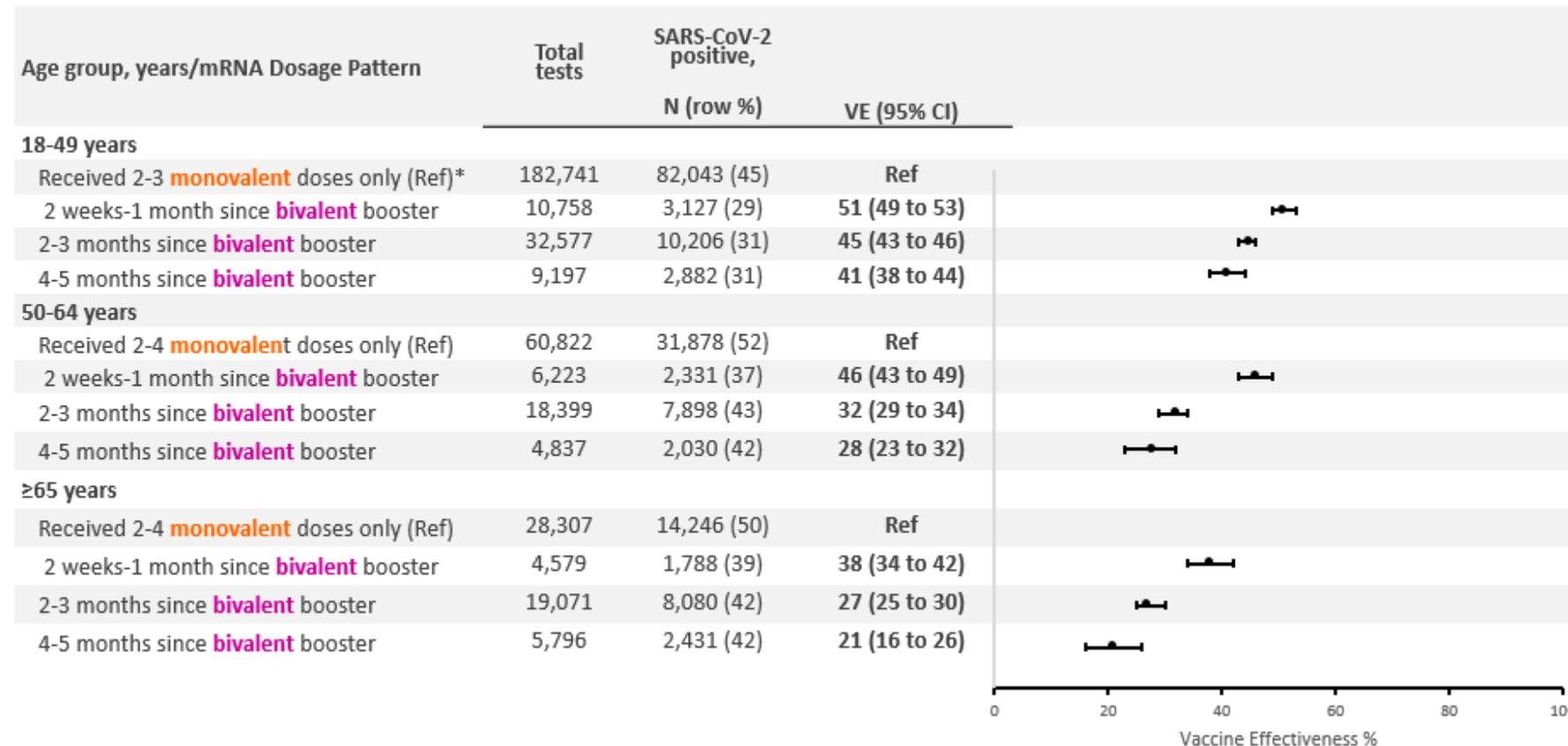


In December 2022, adults ages ≥ 65 years who received a bivalent booster had **12.8X lower risk of hospitalization for COVID-19** compared to **unvaccinated people** and **2.5X lower risk of hospitalization** compared to those vaccinated **without a bivalent booster**

Should older adults be recommended for >1 vaccine annually?

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

- 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



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?

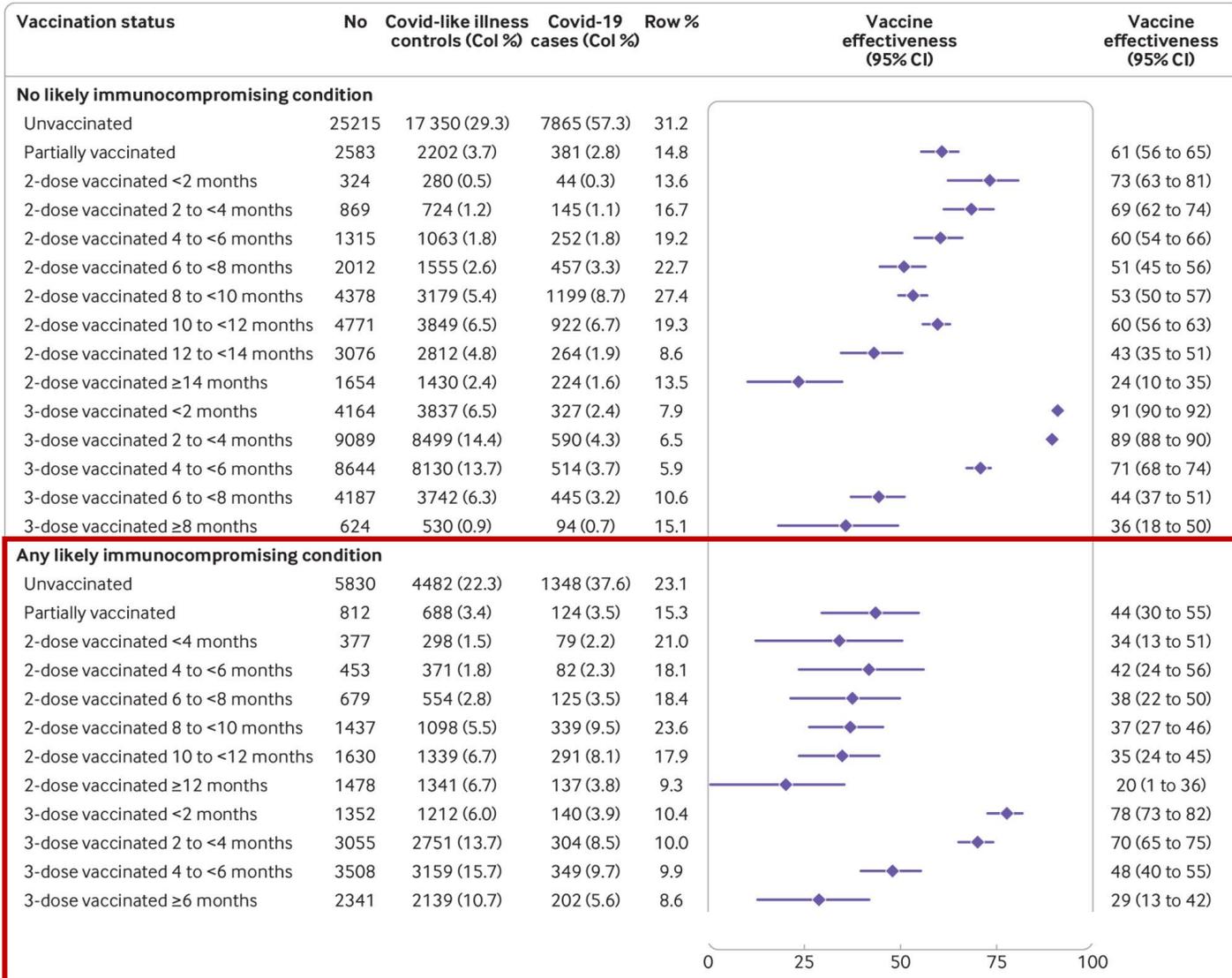
- Numerous studies have demonstrated that mRNA COVID-19 vaccine effectiveness among immunocompromised persons is **lower** than that of immunocompetent persons, including within the period of Omicron predominance
- This has been demonstrated across a range of immunocompromising conditions, and is particularly 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

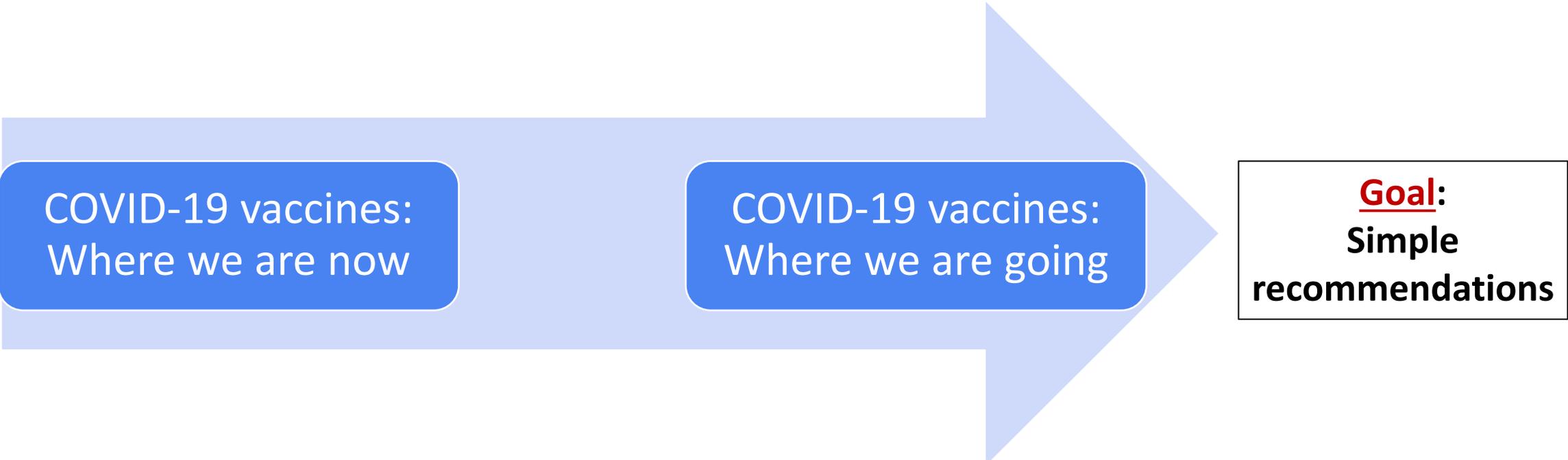
Should people with immunocompromise be recommended for >1 vaccine annually?

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



COVID-19 vaccines:
Where we are now

COVID-19 vaccines:
Where we are going

Goal:
Simple
recommendations

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

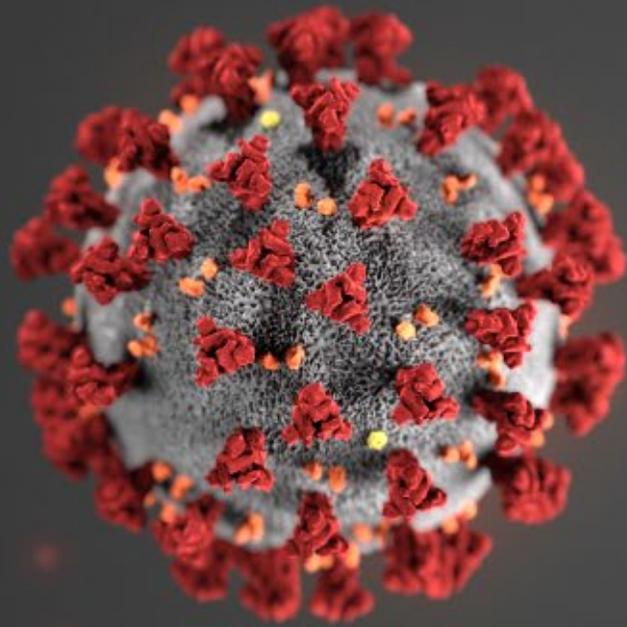
- **Simple recommendations** are easier to communicate, which may improve uptake
 - The Work Group was very supportive of simplified recommendations and planning for future COVID-19 vaccines, which could include updated COVID-19 vaccines
- **Uncertainties remain** for ideal timing and populations for 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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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
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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.

