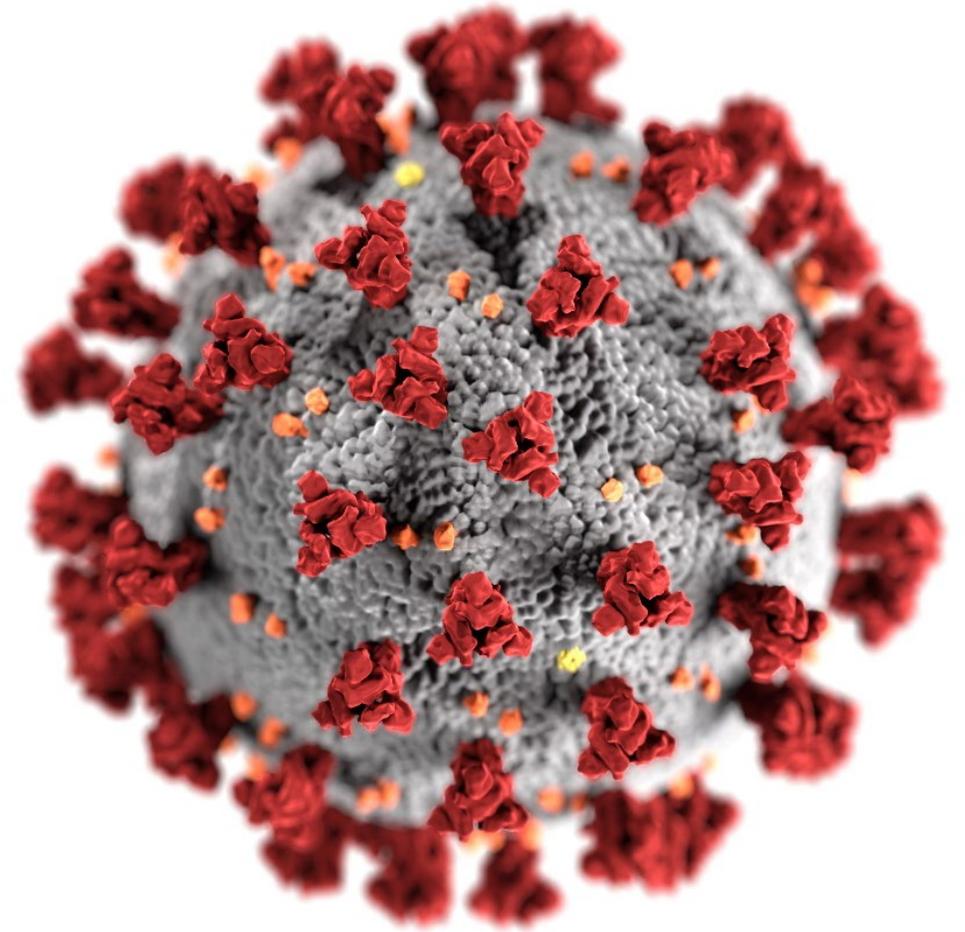


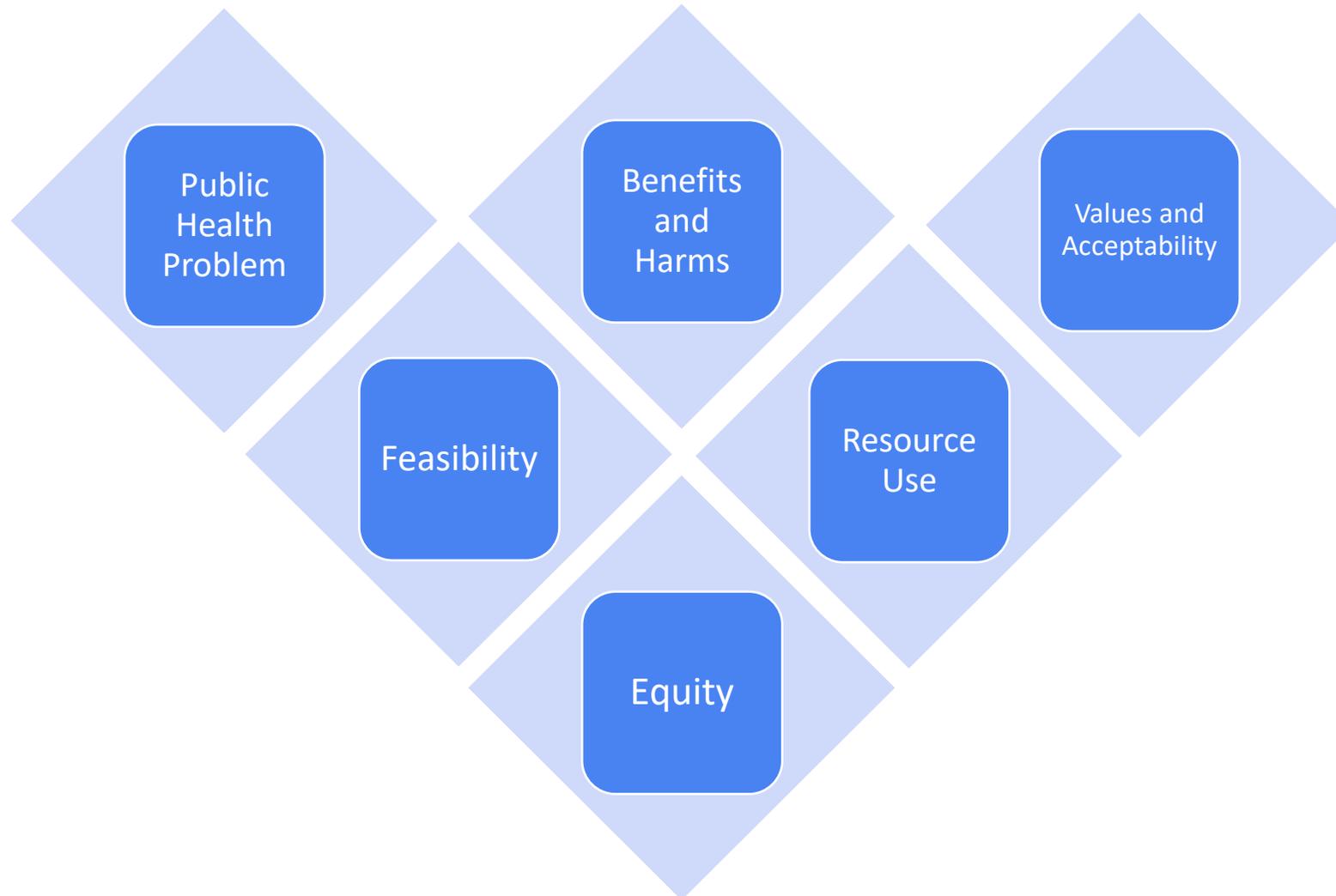
Updates to the Evidence to Recommendation Framework: Pfizer-BioNTech vaccine booster doses in 12–15 year olds

Sara Oliver, MD, MSPH
ACIP Meeting
January 5, 2022

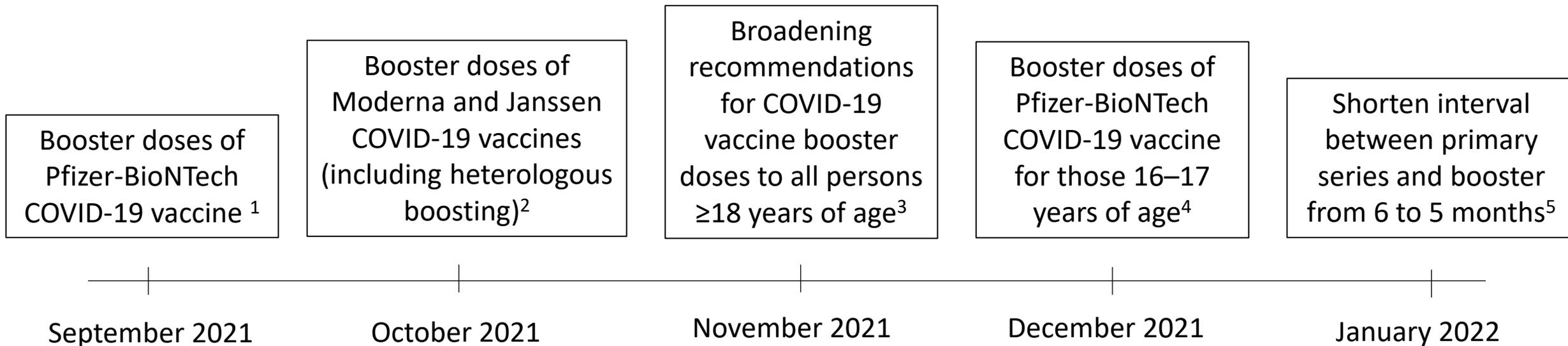


cdc.gov/coronavirus

Evidence to Recommendations (EtR) Framework

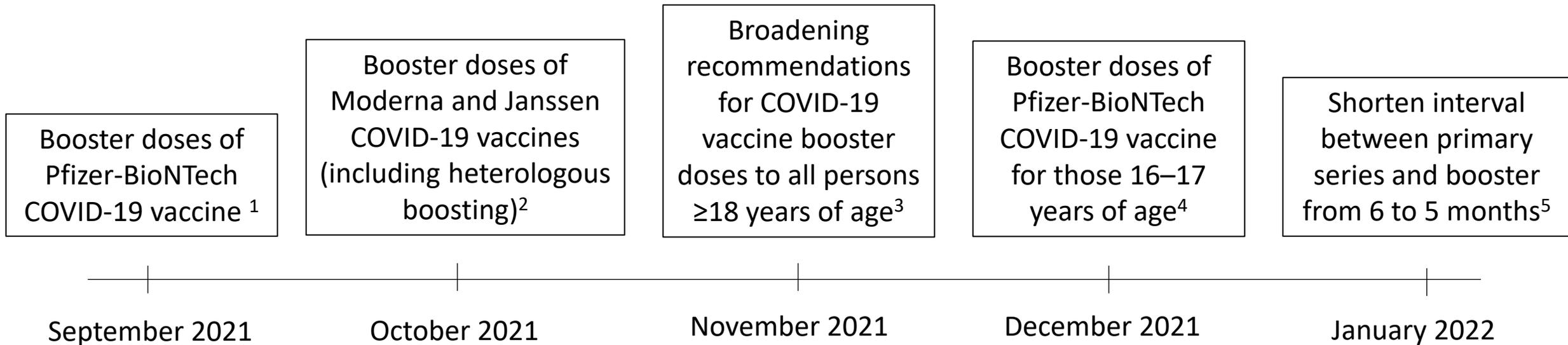


Timeline of recommendations for COVID-19 vaccine booster doses



1. ACIP Meeting, September 23rd <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html>
2. ACIP Meeting, October 21st <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-10-20-21.html>
3. ACIP Meeting, November 19th <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-19.html> and CDC Director's Memo: <https://www.cdc.gov/media/releases/2021/s1129-booster-recommendations.html>
4. CDC's Director's Memo: <https://www.cdc.gov/media/releases/2021/s1208-16-17-booster.html>
5. CDC's Director's Memo: <https://www.cdc.gov/media/releases/2022/s0104-Pfizer-Booster.html>

Timeline of recommendations for COVID-19 vaccine booster doses



Consider booster doses of Pfizer-BioNTech COVID-19 vaccine for those **12–15 years of age**

1. ACIP Meeting, September 23rd <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html>
2. ACIP Meeting, October 21st <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-10-20-21.html>
3. ACIP Meeting, November 19th <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-19.html> and CDC Director's Memo: <https://www.cdc.gov/media/releases/2021/s1129-booster-recommendations.html>
4. CDC's Director's Memo: <https://www.cdc.gov/media/releases/2021/s1208-16-17-booster.html>
5. CDC's Director's Memo: <https://www.cdc.gov/media/releases/2022/s0104-Pfizer-Booster.html>

Current recommendations for COVID-19 vaccine booster doses

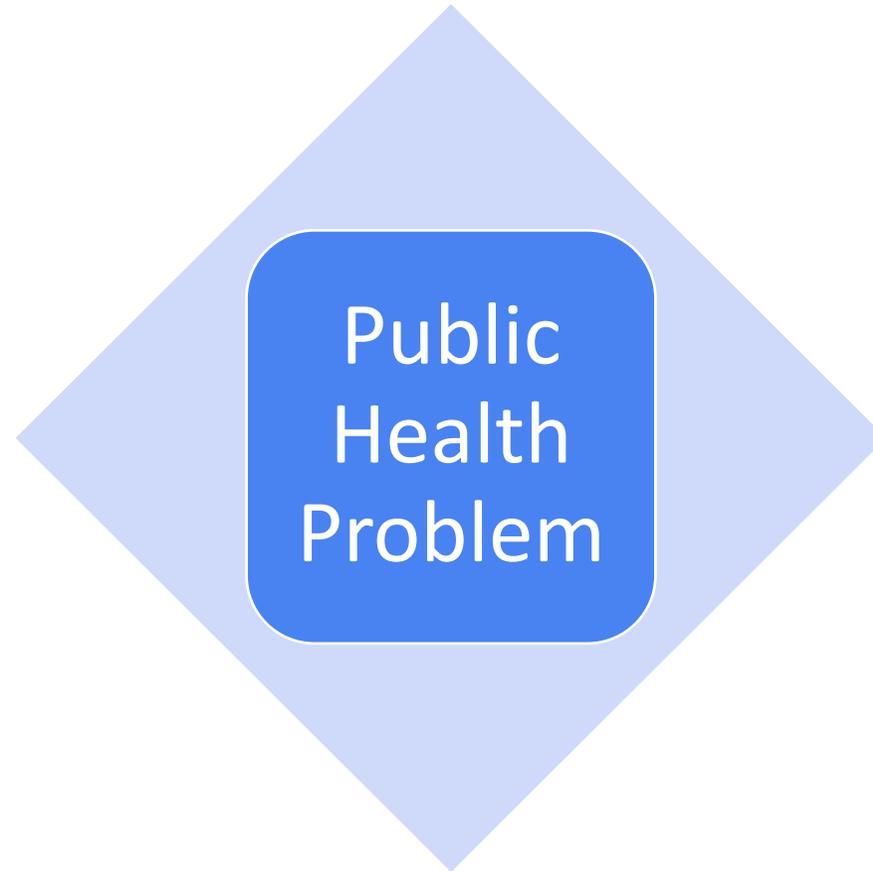
Age	Pfizer-BioNTech COVID-19 vaccine primary series	Moderna COVID-19 vaccine primary series	Janssen COVID-19 vaccine primary series
≥18 years	Should receive a booster <u>5 months</u> after receipt of primary series dose	Should receive a booster <u>6 months</u> after receipt of primary series dose	Should receive a booster <u>2 months</u> after receipt of primary series dose
16–17 years	May receive a booster <u>5 months</u> after receipt of primary series dose	Not authorized	Not authorized

Policy question

- Should individuals **12–15 years of age** receive a Pfizer-BioNTech COVID-19 vaccine booster dose at least **5 months** after completion of the primary series, based on the balance of benefits and risks?

Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



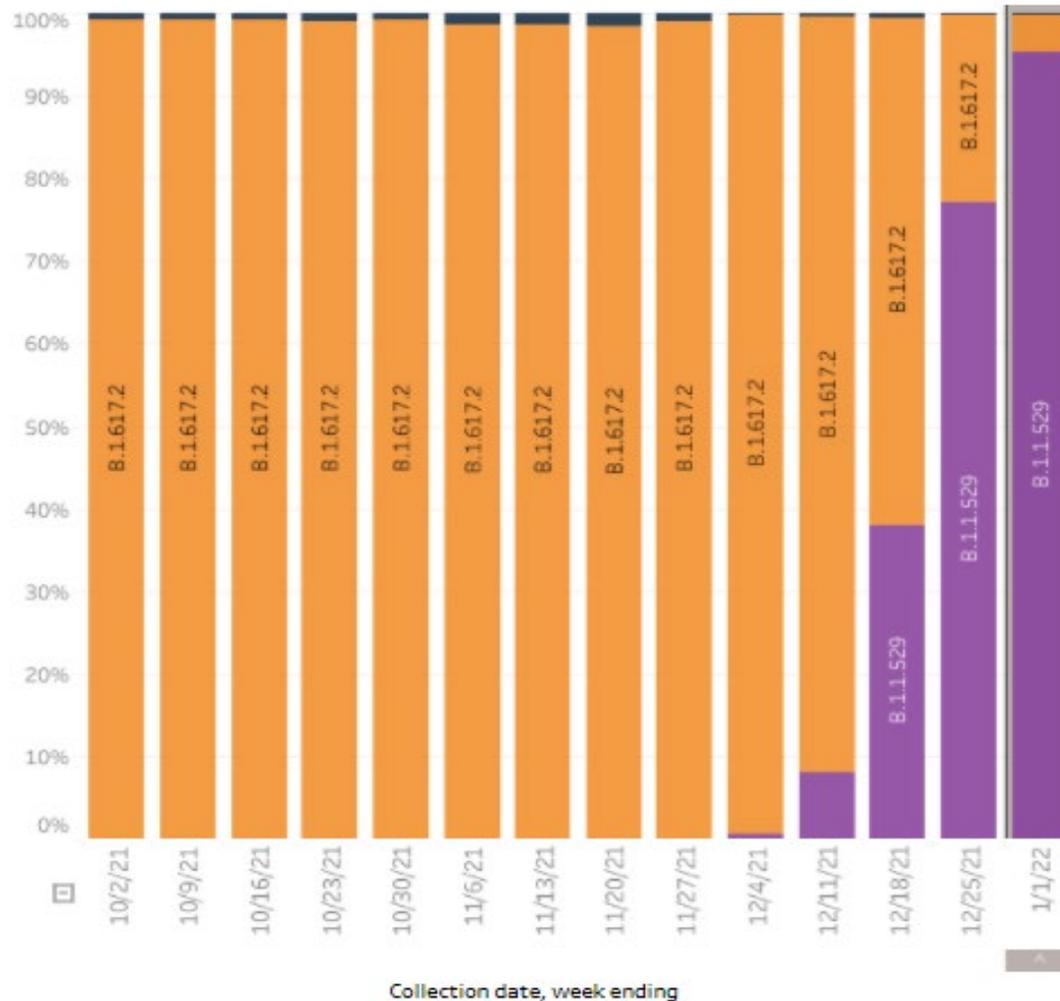
Trends in COVID-19 cases in the United States

January 23, 2020 – January 3, 2022



Estimated circulating SARS-CoV-2 variants in the United States

Variant Proportions, September 19 – Jan 1, 2021



USA				
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	B.1.1.529	VOC	95.4%	92.9-97.0%
Delta	B.1.617.2	VOC	4.6%	2.9-7.0%
Other	Other*		0.0%	0.0-0.1%

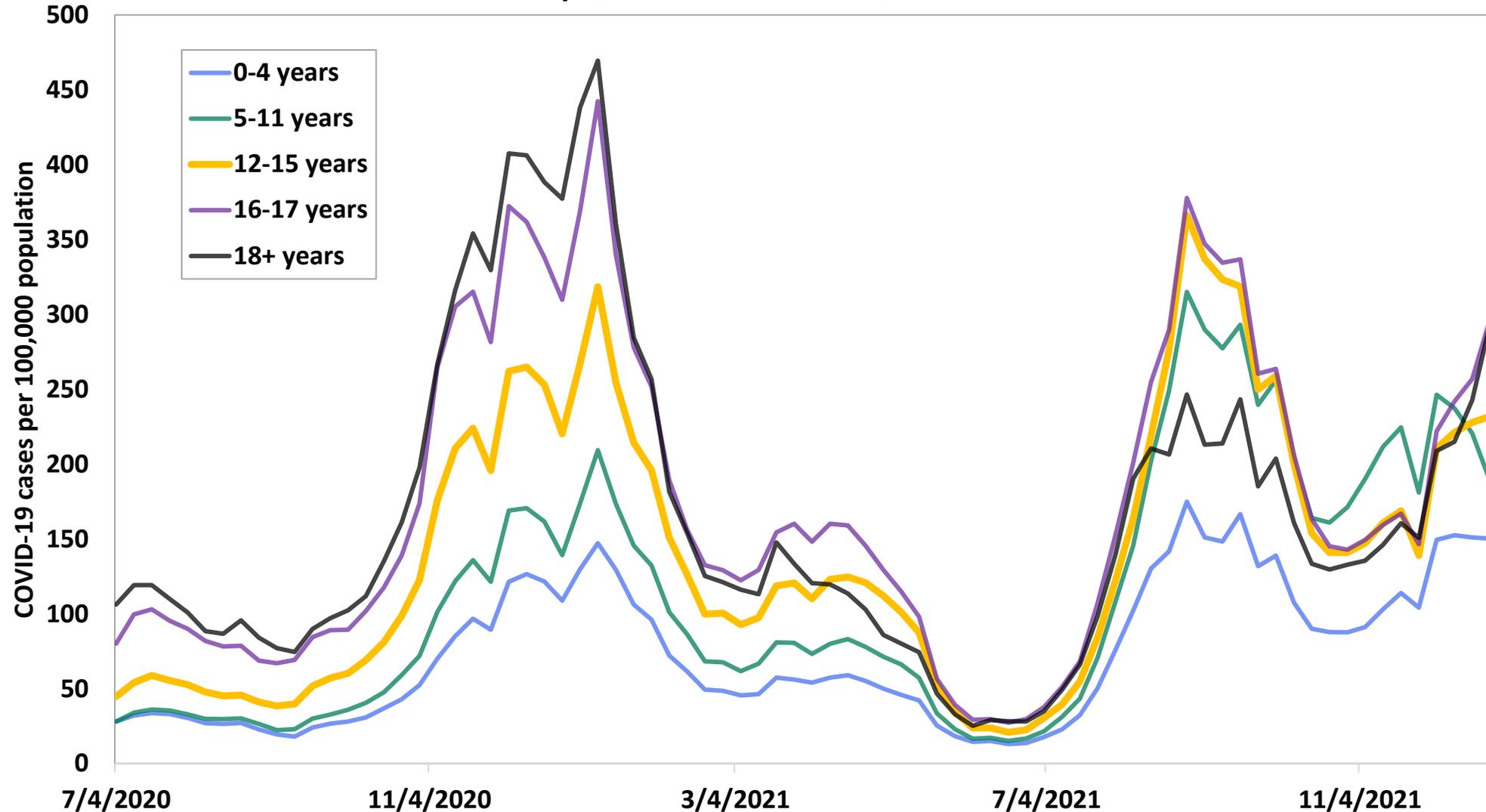
* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

AY.1-AY.127 and their sublineages are aggregated with B.1.617.2. BA.1, BA.2 and BA.3 are aggregated with B.1.1.529.

COVID-19 incidence rates, by age group

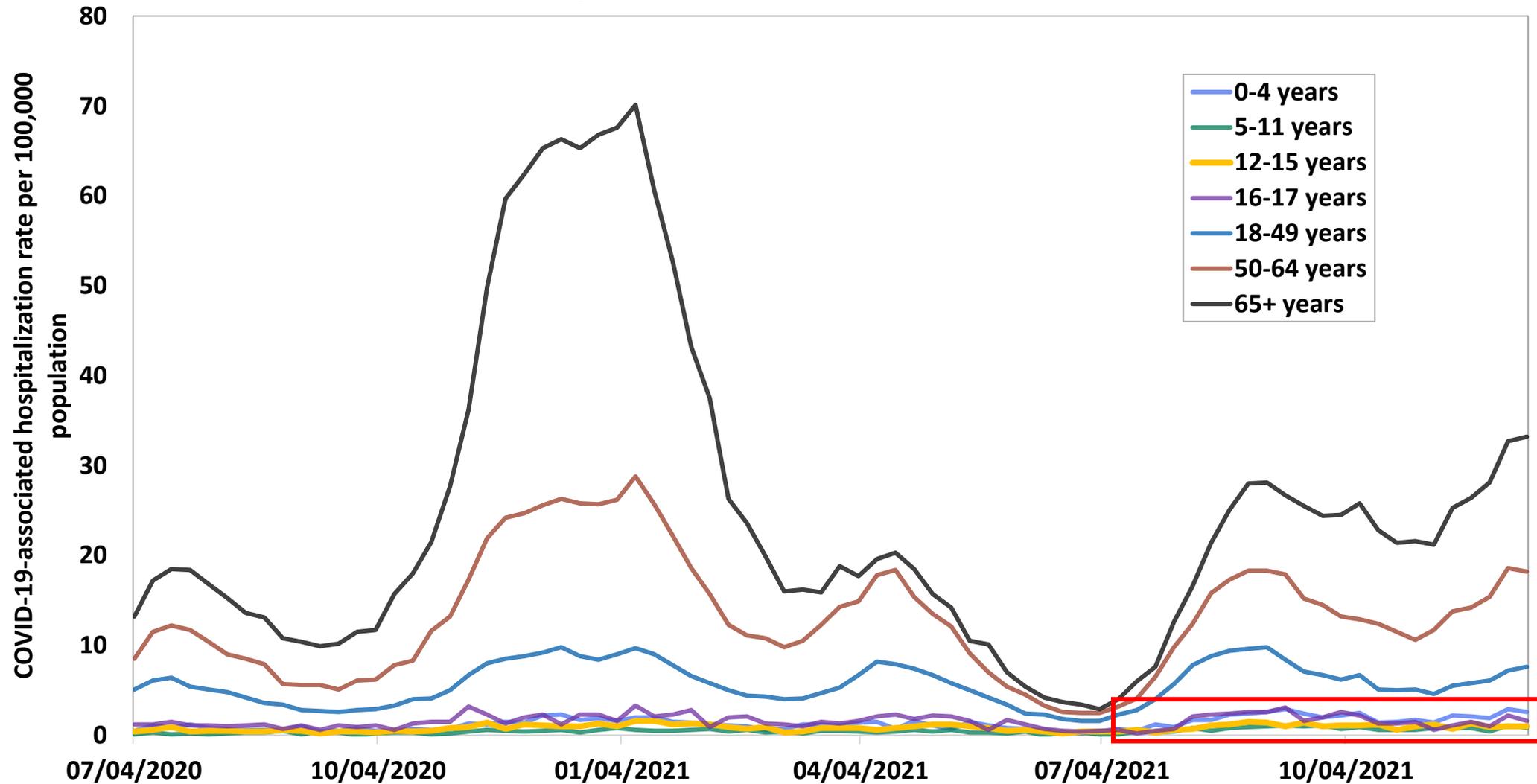
July 4, 2020 – December 25, 2021



Source: <https://covid.cdc.gov/covid-data-tracker/#demographicsovertime>

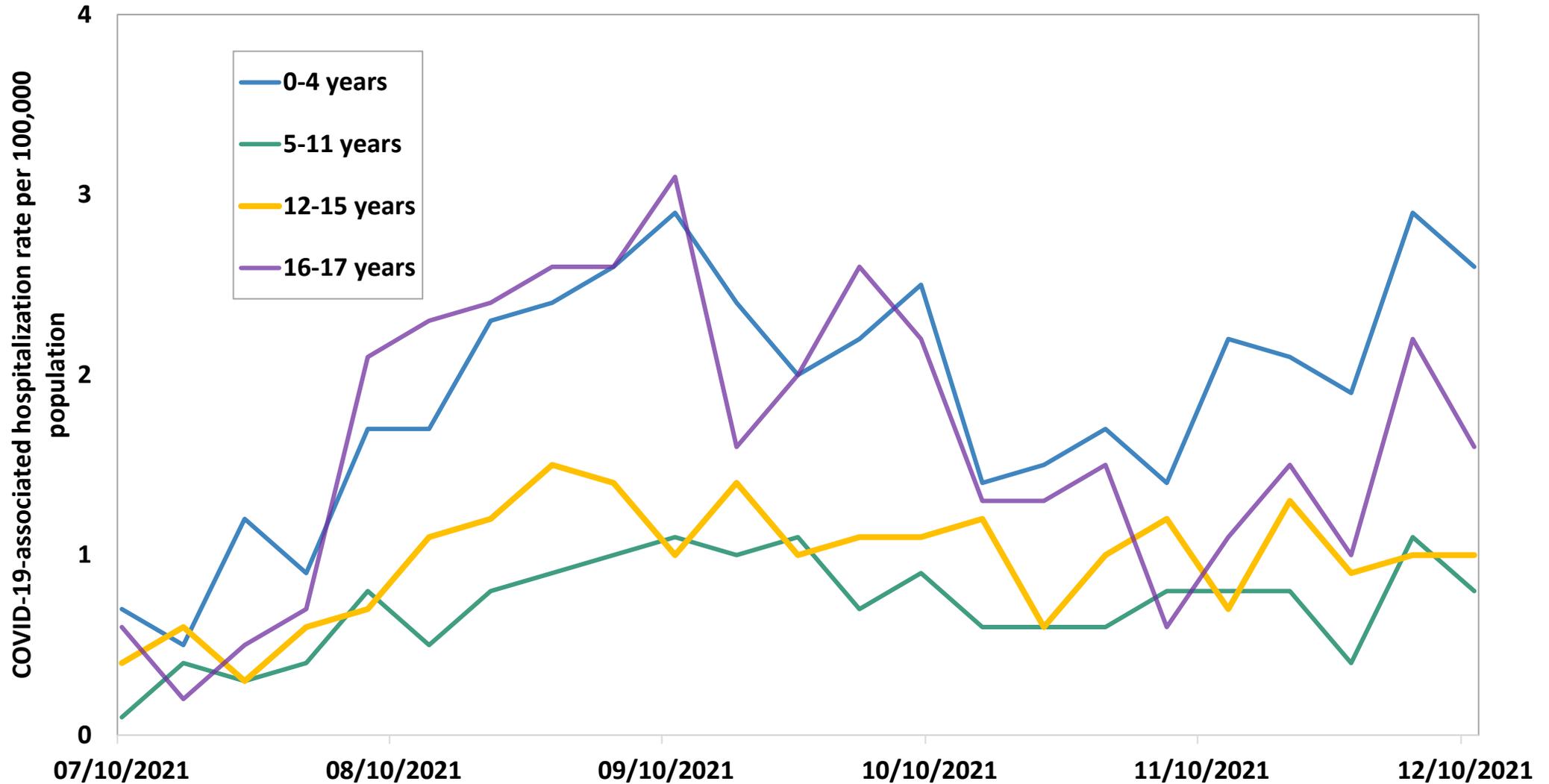
COVID-19-associated hospitalization rates, by age group

July 4, 2020 – December 11, 2021



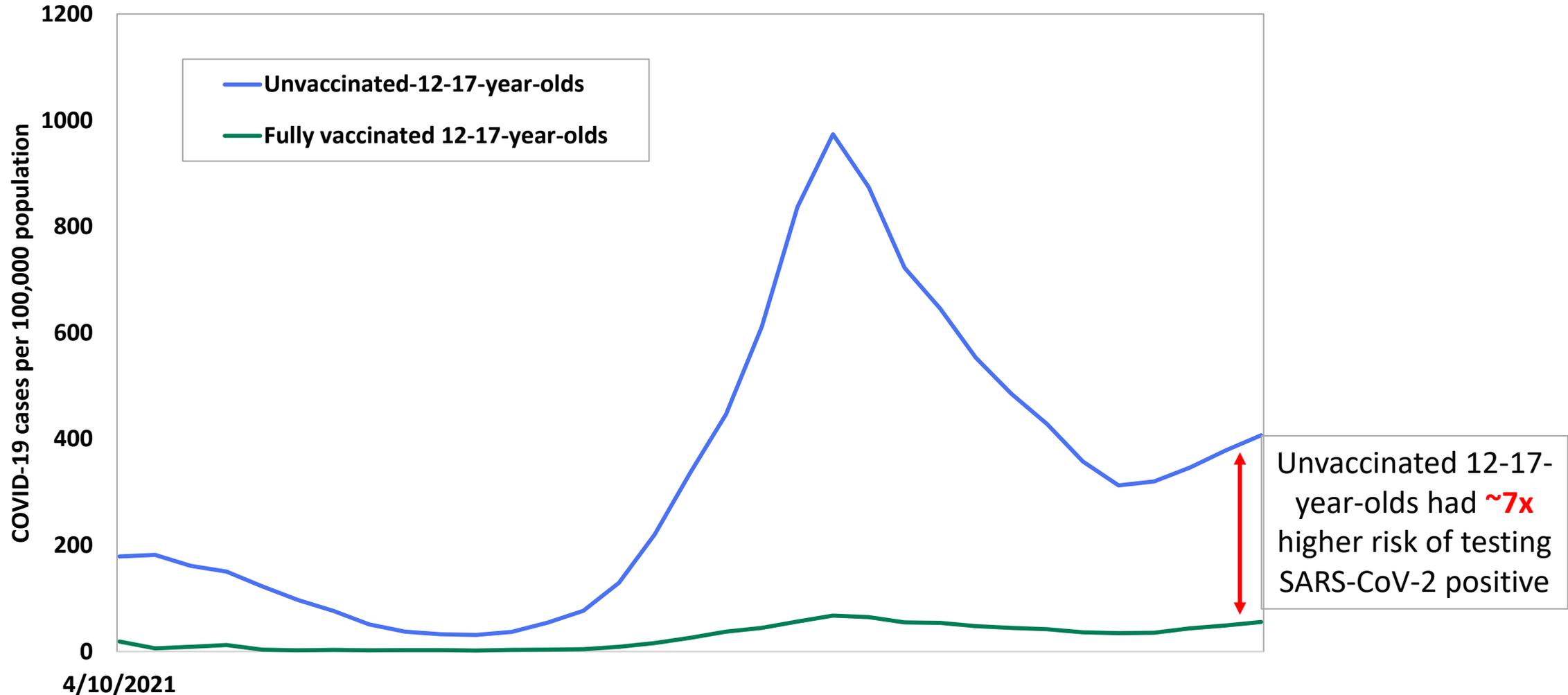
COVID-19-associated hospitalization rates among pediatric age groups

July 10, 2021 – December 11, 2021

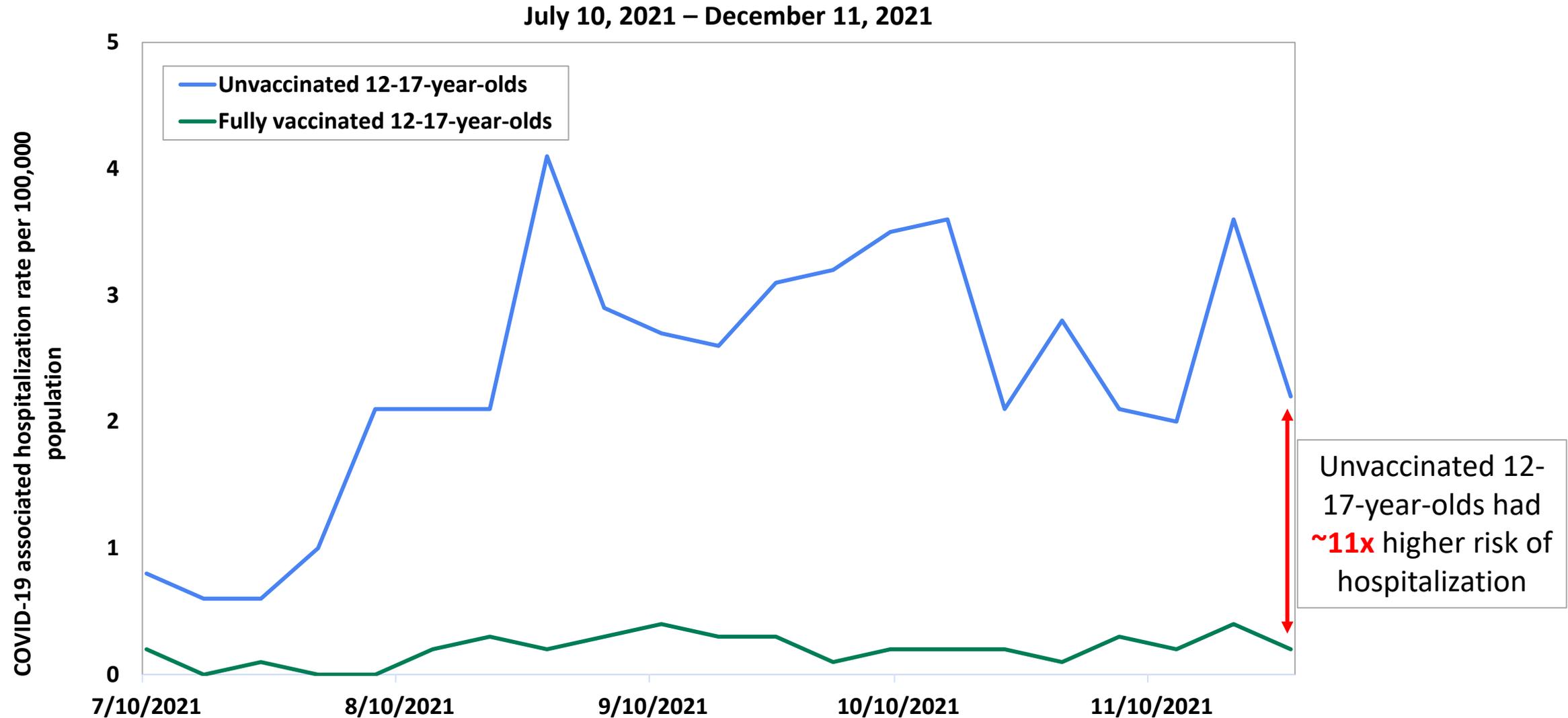


COVID-19-incidence rates among 12–17-year-olds, by vaccination status

July 10, 2021 – November 20, 2021



COVID-19-associated hospitalization rates among 12–17-year-olds, by vaccination status



Estimate of Vaccine Effectiveness of Pfizer-BioNTech COVID-19 Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021

- **Design:** prospective cohort study
- **Period:** July 25th –December 4th
- **Population:** children and adolescents, aged 12–17 years in the PROTECT prospective cohort study. PROTECT participants in Arizona were recruited from families of adults participating in the HEROES study and the general public
- **Adjusted using:** inverse probability of treatment weighting approach with individual propensities to be vaccinated during each week based on sociodemographic characteristics, health information, frequency of close social contact, percentage of time wearing masks, and local virus circulation

Estimate of Vaccine Effectiveness of Pfizer-BioNTech COVID-19 Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021

Pfizer COVID-19 vaccination status	No. of contributing participants*	Total person-days	No. of days, median (IQR)	No. of SARS-CoV-2 infections	VE, % (95% CI)	
					Unadjusted	Adjusted ^{†,§}
Unvaccinated	66	4,288	62 (23–98)	16	—	—
Partially vaccinated (≥14 days after dose 1 to day 13 after dose 2)	30	909	21 (20–28)	0	—	—
Fully vaccinated (≥14 days after dose 2)	190	21,693	119 (105–133)	5	94 (83–98)	92 (79–97)

* Contributing participants in vaccination categories did not equal the number of participants in the study because participants could contribute to more than one vaccination category since vaccination status varies by time.

† Adjusted VE is inversely weighted for propensity to be vaccinated; all covariates met balance criteria of standardized mean difference (SMD) < 0.2 after weighting except community mask use and local virus circulation (SMD = 0.228 and 0.288, respectively), but community mask use was only found to change VE estimate by ≥ 5% when added to the model and was therefore included as a covariate in the Cox regression model for VE.

§ Five participants missing community mask use were excluded from analysis; this exclusion did not affect the VE estimate.

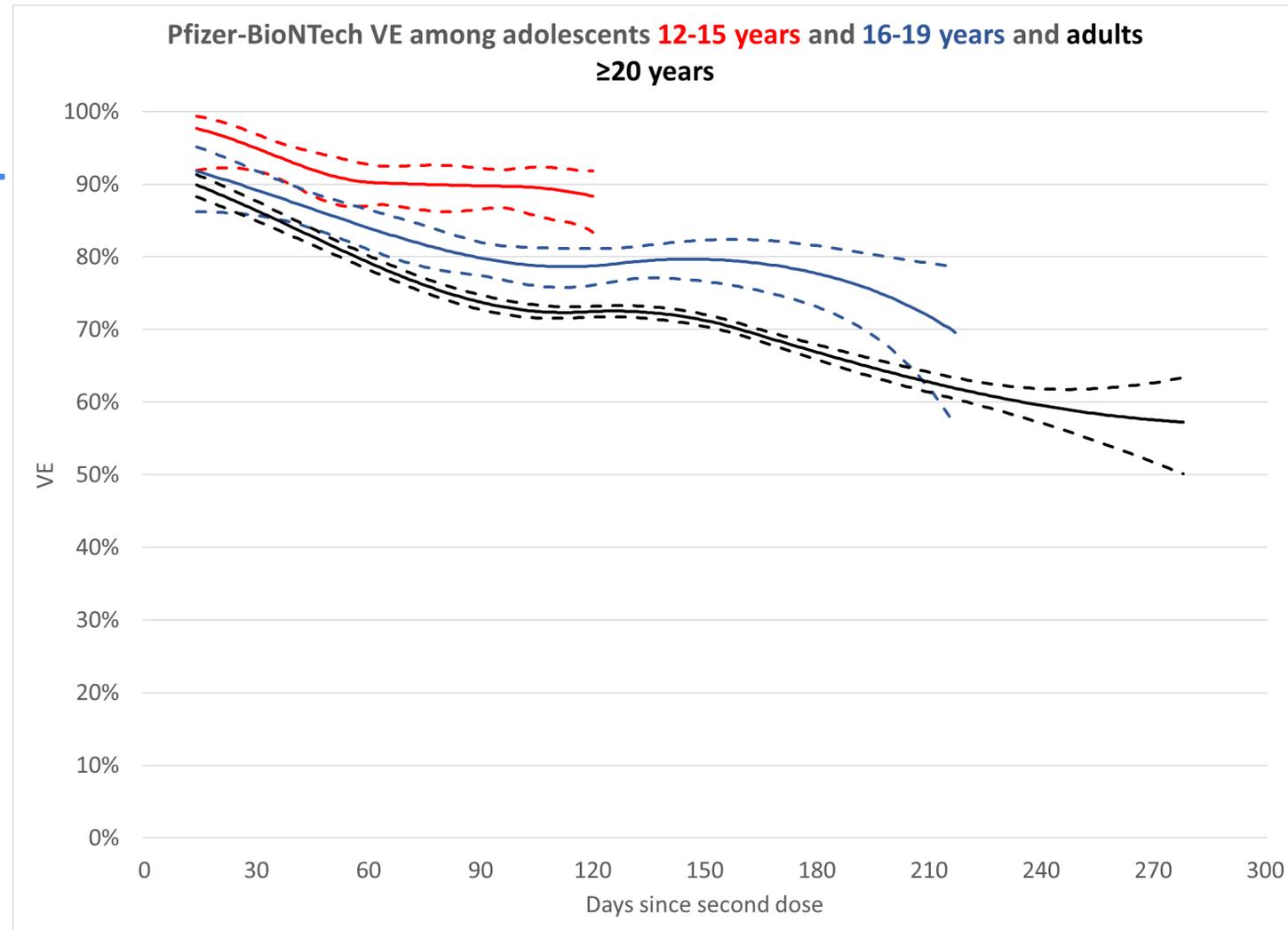
Increasing Community Access to Testing (ICATT) Partnership: VE analysis for symptomatic infection, July 18–October 17, 2021

- Nationwide community-based COVID-19 drive-through testing at pharmacies
- Self-reported vaccine history at time of registration for COVID-19 testing; excluded those who did not report vaccination status (~4% of records among adolescents)
- **Design:** Test-negative, case-control assessment
- **Period:** July 18-October 17 (Delta variant represented >90% of nationally sequenced specimens)
- **Population:** Persons aged 12-15, 16-19, ≥20 years with COVID-like illness (CLI) and laboratory-based nucleic acid amplification testing (NAAT)
- **Adjusted for:**
 - Calendar day, race, ethnicity, gender, site's state, site census tract's social vulnerability index (SVI)
 - **Not** adjusted for underlying conditions or prior infection

Comparison of Pfizer-BioNTech VE against symptomatic infection between **adolescents 12-15** and **16-19 years** and **adults ≥ 20 years** and day since the second dose, July 18-October 17

- VE is highest among ages 12-15 years, then 16-19 years, then adults ≥ 20 years
- VE wanes among all age groups with increasing time since vaccination
- Analysis reflects period with predominance of Delta variant

Confidence intervals shown in dotted lines. The presented (fitted) curves are truncated on the day with ≤ 10 cases observed beyond it to avoid presenting wide confidence bounds.



- 12-15 years
- 16-19 years
- Adults ≥ 20 years

Effectiveness of Pfizer-BioNTech mRNA Vaccination Against COVID-19 Hospitalization Among Persons Aged 12–18 Years — United States, June–September 2021

- **Design:** test negative, case control
- **Period:** June 1st – September 30th
- **Population:** children and adolescents, aged 12-18 years hospitalized at 19 pediatric hospitals in 16 states
- **Adjusted for:** census region, calendar month of admission, age, sex, race/ethnicity

Vaccine effectiveness against COVID-19 hospitalization among patients aged 12–18, 19 pediatric hospitals, 16 states, July – September, 2021

Age group, yrs	No. vaccinated/Total (%)		Vaccine effectiveness, % (95% CI)
	Case-patients	Controls	
All	6/179 (3.4)	93/285 (32.6)	93 (83–97)
12–15	4/106 (3.8)	53/179 (29.6)	91 (74–97)
16–18	2/73 (2.7)	40/106 (37.7)	94 (78–99)

- **Limitation:** VE estimate reflects Delta dominant period

Effectiveness of Pfizer-BioNTech COVID-19 vaccine against MIS-C

- Using a test-negative case-control design that included 102 MIS-C case-patients and 181 hospitalized controls 12–18 years of age:
 - Vaccine effectiveness of 2-doses of the Pfizer-BioNTech vaccine against MIS-C was **91%** (95% CI = 78%–97%)
 - This estimate was calculated in consideration of children hospitalized a minimum of 28 days after receipt of their 2nd dose
 - 97/102 (95%) of hospitalized children with MIS-C were unvaccinated
 - None of the five vaccinated MIS-C patients required respiratory or cardiovascular life support (invasive mechanical ventilation, vasoactive infusions, or ECMO) compared to 38/97 (39%) of unvaccinated MIS-C patients

Summary

Public Health Problem

- US experiencing substantial **increase** in cases over last month
- **Omicron** variant represents over half of recent U.S. cases
- COVID-19 cases and hospitalizations **7–11 times higher** in unvaccinated adolescents, compared to vaccinated adolescents
- Vaccine effectiveness in adolescents 12–15 years of age remains high, but may have some waning over time
 - Current VE estimates primarily in the setting of the **Delta variant**

Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



Randomized controlled trial data evaluated for recommendation of primary series in 12–15-year-olds

- Pfizer-BioNTech phase 2/3 randomized controlled trial (RCT)
- ~2,000 persons aged 12–15 years in United States
- Data evaluated: all eligible randomized participants who received all vaccinations as randomized within the predefined window and no other important protocol deviations (data cut-off: March 13, 2021)

Summary of the phase 2/3 trial data, primary series in 12-15-year-olds: Benefits

- The clinical trial for the Pfizer-BioNTech COVID-19 vaccine demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. There were no COVID-19 cases among the 1,001 vaccine recipients and 16 COVID-19 cases among 972 placebo recipients for a vaccine efficacy of **100%**
- The geometric mean ratio (GMR) for antibodies in 12–15-year-olds compared with 16–25-year-olds was 1.76 (95% CI:1.47, 2.10), and **met the noninferiority criteria**
- No hospitalizations due to COVID-19 or cases of MIS-C were reported by any trial participants

Summary of the phase 2/3 trial data, primary series in 12-15-year-olds: Harms

- Serious adverse events (SAE) were reported in a higher proportion of recipients of vaccine versus placebo (0.4% vs 0.2%) based on 5 SAEs in the vaccine group and 2 in the placebo group
- Severe reactions were more common in vaccine recipients; a grade ≥ 3 reaction was reported by 10.7% of vaccinated versus 1.9% of placebo group

Rate ratio for infection, booster doses compared to primary series

Israel, July 30–October 10, 2021

- Real world effectiveness data from Israel: 4.7 million individuals ≥ 16 years of age
 - Booster dose given 5 months after a 2-dose Pfizer-BioNTech COVID-19 vaccine primary series demonstrated efficacy against confirmed infection in all age groups
 - Among 16–29 year olds, the rate ratio for infection in the non-boosted group vs boosted group was **17.2**

Age group	Rate Ratio (95% CI)
≥ 60 yr	12.3 (11.8–12.8)
50–59 yr	12.2 (11.4–13.0)
40–49 yr	9.7 (9.2–10.3)
30–39 yr	9.0 (8.4–9.7)
16–29 yr	17.2 (15.4–19.2)

Myocarditis in Israel

Reported after Pfizer-BioNTech COVID-19 vaccine, as of December 15, 2021

	Age (years)	Post-dose 1 Rate per 100,000	Post-dose 2 Rate per 100,000	Post-dose 3 Rate per 100,000	Number of 3 rd dose delivered
Females	12-15	0	0.6	0	3,156
	16-19	0	0.9	1.6	125,088
	20-24	0.4	2.0	0	171,870
	25-29	0	0.9	0	156,673
	≥30	0.1	0.4	0.1	1,658,035
Males	12-15	0.5	6.6	0	3,178
	16-19	1.2	15.3	6.5	123,355
	20-24	2.1	10.5	4.7	171,235
	25-29	1.1	8.3	0.6	162,360
	≥30	0.3	1.5	1.0	1,554,155

Rates of myocarditis after a third dose likely **lower** than what is seen after second dose

Myocarditis in Israel

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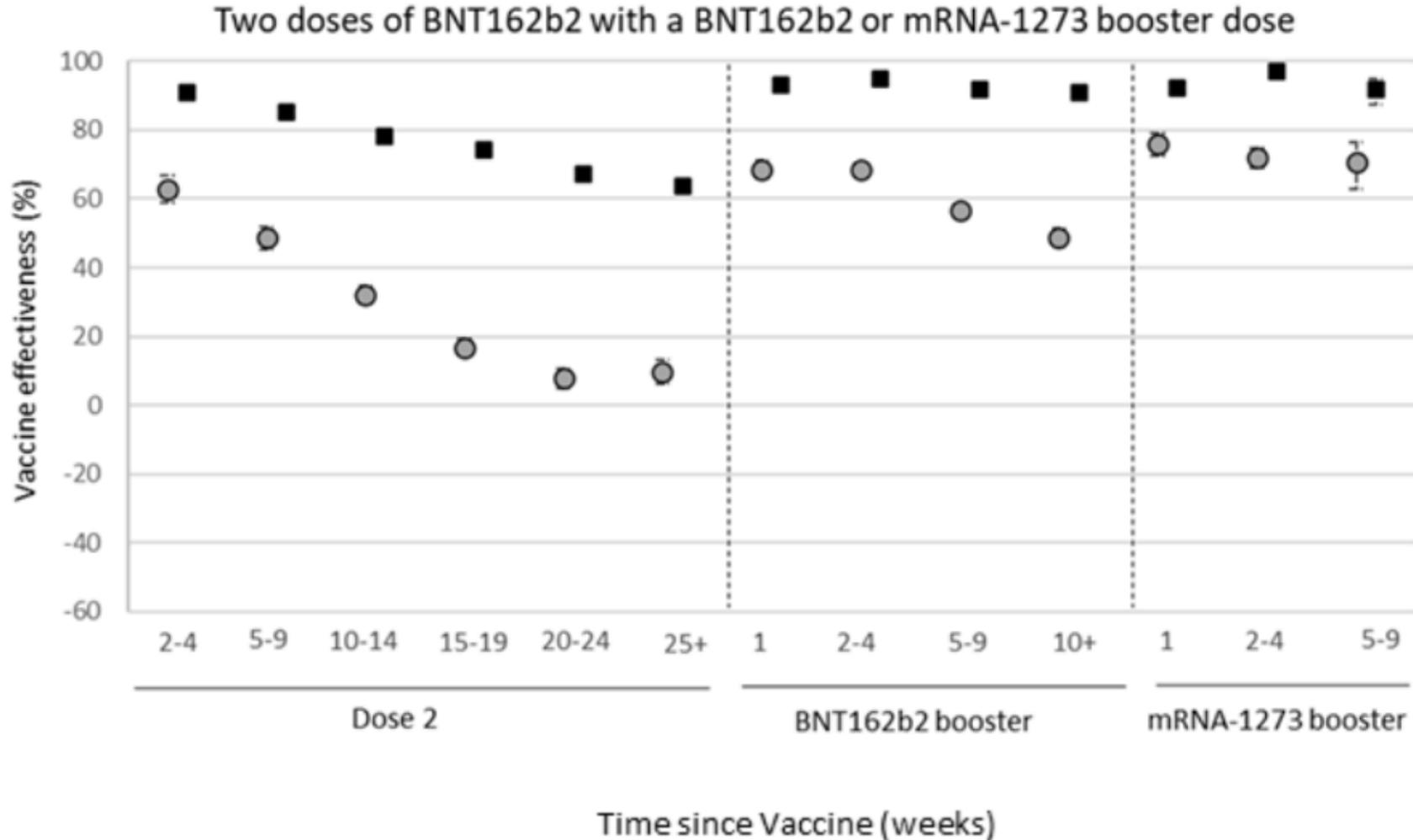
No cases of myocarditis reported after a 3rd dose in 12–15 year olds, out of **6,334** doses provided

Neutralization of Omicron variant by sera from vaccinees

- Neutralization of Omicron below the limit of detection for most individuals who received two doses of mRNA or one dose of Janssen vaccines
- Neutralization of Omicron above the limit of detection in many vaccinated people who received a booster or who were previously infected
- Given limits of detection of assays, difficult to evaluate with laboratory tests whether people have the level of antibodies needed to protect against severe disease

Wilhelm et al. <https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v1.full.pdf>; Cele et al. <https://www.medrxiv.org/content/10.1101/2021.12.08.21267417v2>; Roessler et al. <https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1>; Dejnirattisai et al. <https://www.medrxiv.org/content/10.1101/2021.12.10.21267534v1>; Schmidt et al. <https://drive.google.com/file/d/1zjJWsybGaa3egiyn5nQqTzBtI0kmvMUu/view>; Pfizer investor brief: <https://investors.biontech.de/static-files/47b4131a-0545-4a0b-a353-49b3a1d01789>; Nemet et al. <https://www.medrxiv.org/content/10.1101/2021.12.13.21267670v1>; Ikemura et al. <https://www.medrxiv.org/content/10.1101/2021.12.13.21267761v1>; Lu et al. <https://www.medrxiv.org/content/10.1101/2021.12.13.21267668v1>; Garcia-Beltran et al. <https://www.medrxiv.org/content/10.1101/2021.12.14.21267755v1/>; Cameroni et al. <https://www.biorxiv.org/content/10.1101/2021.12.12.472269v1.full.pdf>; Doria-Rose et al. <https://doi.org/10.1101/2021.12.15.21267805>; Planas et al. <https://www.biorxiv.org/content/10.1101/2021.12.14.472630v1>; Aggarwal et al. <https://www.medrxiv.org/content/10.1101/2021.12.14.21267772v1>; Liu et al. <https://www.biorxiv.org/content/10.1101/2021.12.14.472719v1.full.pdf>

Pfizer mRNA vaccine effectiveness (VE) against infections with Delta and Omicron variants, United Kingdom



- Delta
 - Omicron
- Increased waning immunity for Omicron vs Delta
 - mRNA vaccine booster increased VE against Omicron

Potential benefits of booster dose in 12–15 year olds

- 2-dose primary series of Pfizer-BioNTech COVID-19 vaccine in 12–15 year olds provides protection against COVID-19 symptomatic infection, hospitalization, MIS-C and death
- VE after the primary series is high, but likely impacted by Omicron variant
 - In persons ≥ 18 years of age in the UK: VE was lower for Omicron variant compared to Delta
 - Estimates of VE against Omicron in adolescents 12–15 years of age is unknown
- Booster dose shown to increase neutralization antibody level and VE in persons ≥ 18 years of age
 - In the UK, a booster dose increased VE in the setting of Omicron

Potential harms of booster dose in 12–15 year olds

- Myocarditis rates among 12–15-year-olds who received a primary series lower than rates among 16–17-year-olds
- Among >6,000 12–15-year-olds who received a third dose in Israel, no cases of myocarditis were reported
 - In older age groups, rates of myocarditis after a third dose **lower** than what is seen after second dose

Summary

Benefits and Harms

- In the setting of Omicron, likely lower vaccine effectiveness in all populations, compared to effectiveness seen with Delta variant
- Higher antibody titers improve neutralization of Omicron variant; booster doses of COVID-19 vaccines increase neutralization titers
- Impact of booster dose on neutralizing antibody or VE in adolescents 12–15 years of age is unknown, but likely to provide additional protection
- Myocarditis rates after booster dose likely lower than what is seen after a 2nd dose in younger adolescents

Evidence to Recommendations Framework

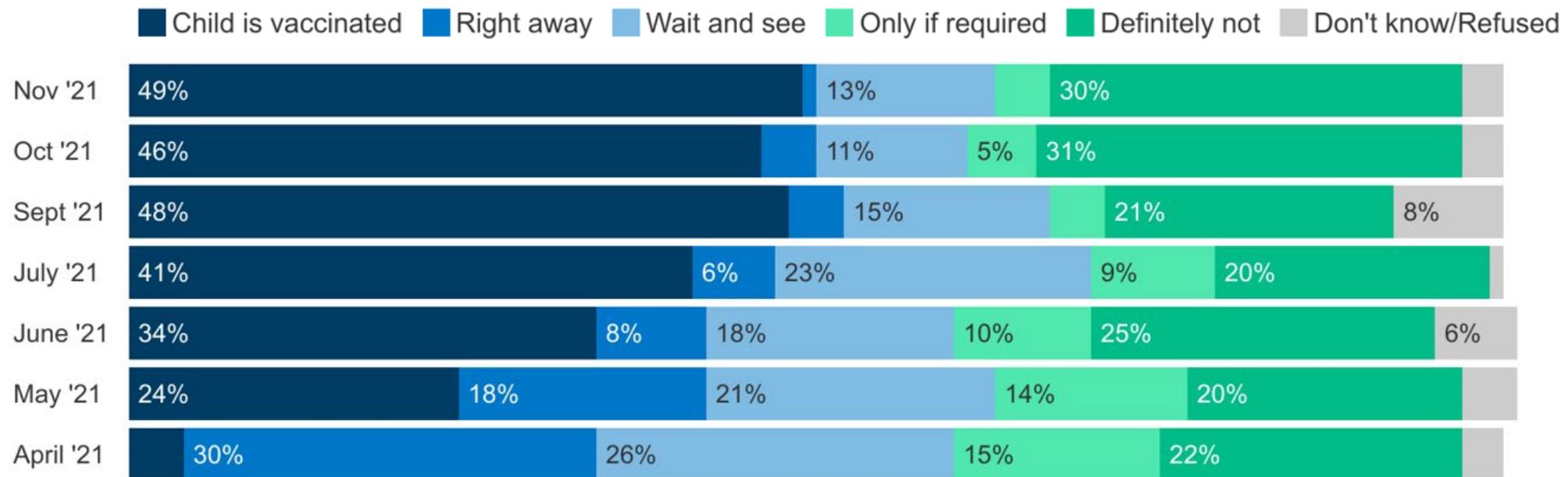
Booster doses of COVID-19 vaccines



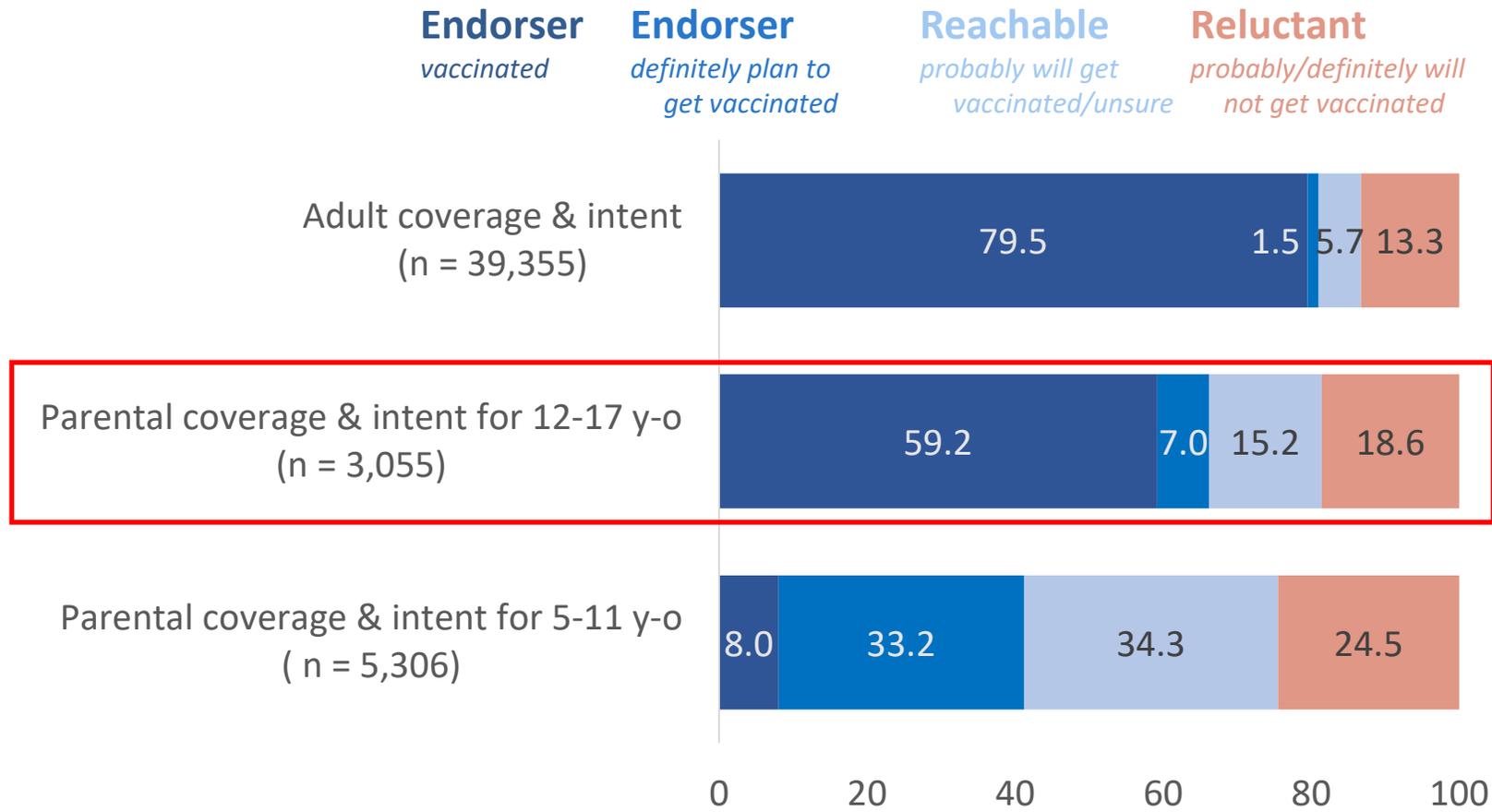
Trends in vaccine uptake among adolescents, 12 – 17 years United States

- Vaccine uptake among 12 – 17-year-olds has slowed, as about half of parents say their teenager has already received at least one dose of the COVID-19 vaccine in November

Thinking about your child between the ages of 12 and 17, have they received at least one dose of a COVID-19 vaccine, or not? If not, do you think you will get them vaccinated...?



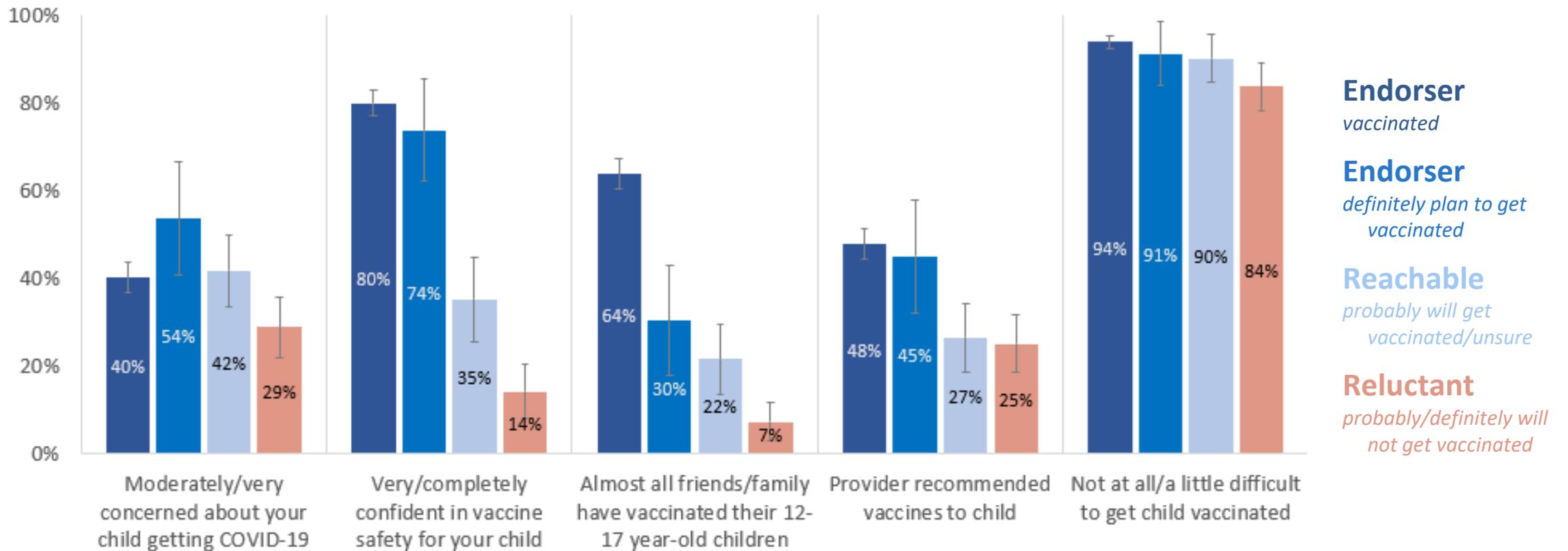
Coverage and intent for vaccination among adults, adolescents, 12 – 17 years and children, 5 – 11 years



- 59% of 12-17-year-olds were vaccinated, but 7% of parents definitely planned to vaccinate their 12-17-year-old (unrealized intent)
- 8% of 5-11-year-olds were vaccinated, 33% of parents definitely planned to vaccinate their child

Behavioral, social and access-factors by vaccination coverage and parental intent for adolescents aged 12 – 17 years

NIS-CCM – Oct 31, 2021 – Nov 27, 2021, n=3,055



Parental confidence in safety of COVID-19 vaccines for adolescents and children

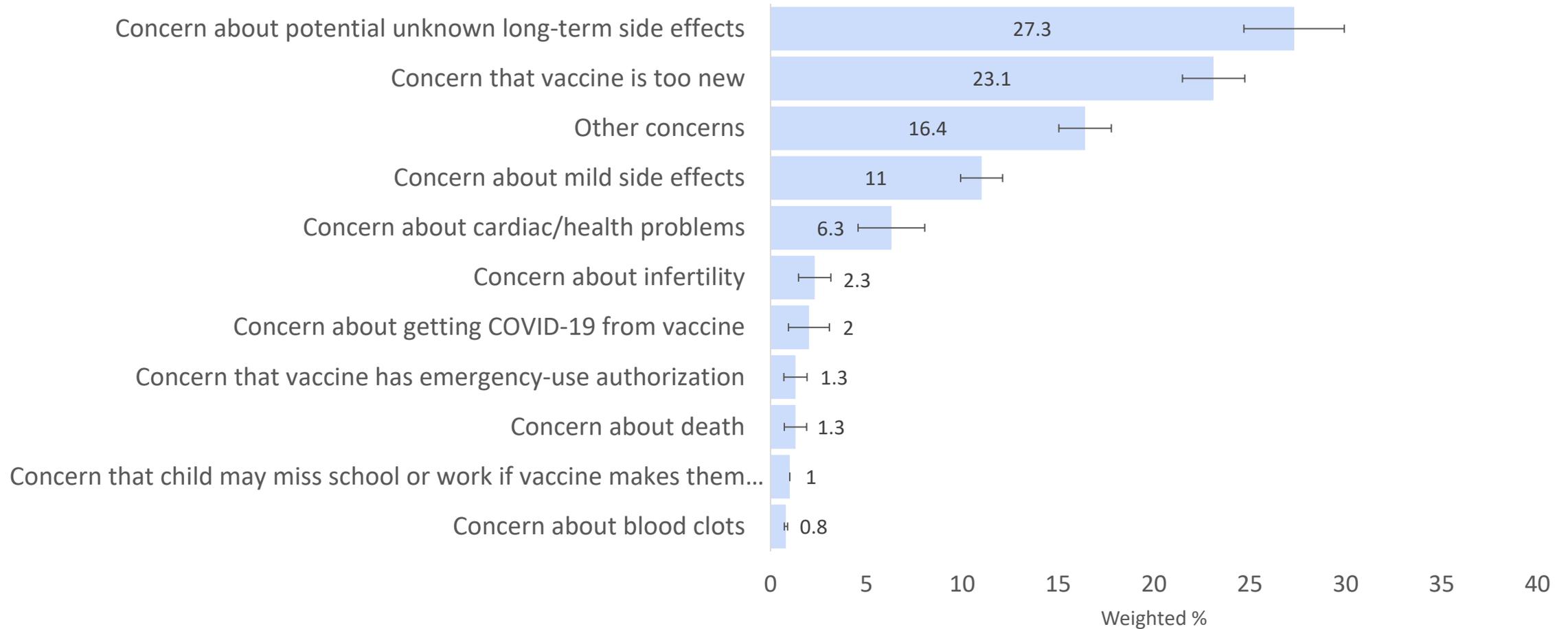
- Parents are less likely to express confidence that COVID-19 vaccines are safe for adolescents or children
- Majority of parents say they do not have enough information on vaccine effectiveness (58%), side effects (63%) and safety (61%) in children
 - Survey respondents were asked, “How confident, if at all, are you that the COVID-19 vaccines are safe for...?”

■ Very confident ■ Somewhat confident ■ Not too confident ■ Not at all confident



Parental concern about safety of COVID-19 vaccines in adolescents

NIS-CCM – Oct 31, 2021 – Nov 27, 2021, n=877

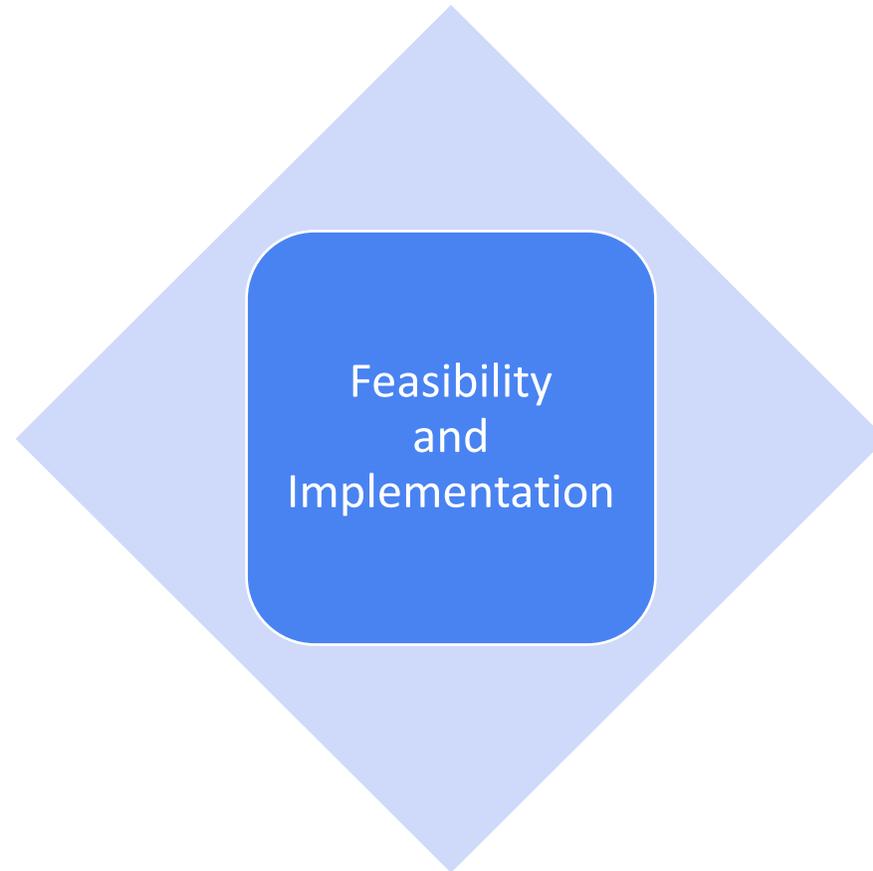


Summary

- Vaccine uptake among 12-17-year-olds has slowed over the past two months
 - As more information emerges on the potential impact of the Omicron variant in children, parents' attitudes towards vaccinating their teenagers and younger children for COVID-19 may change
- Parents of adolescents and children are concerned about the potential unknown long-term side effects

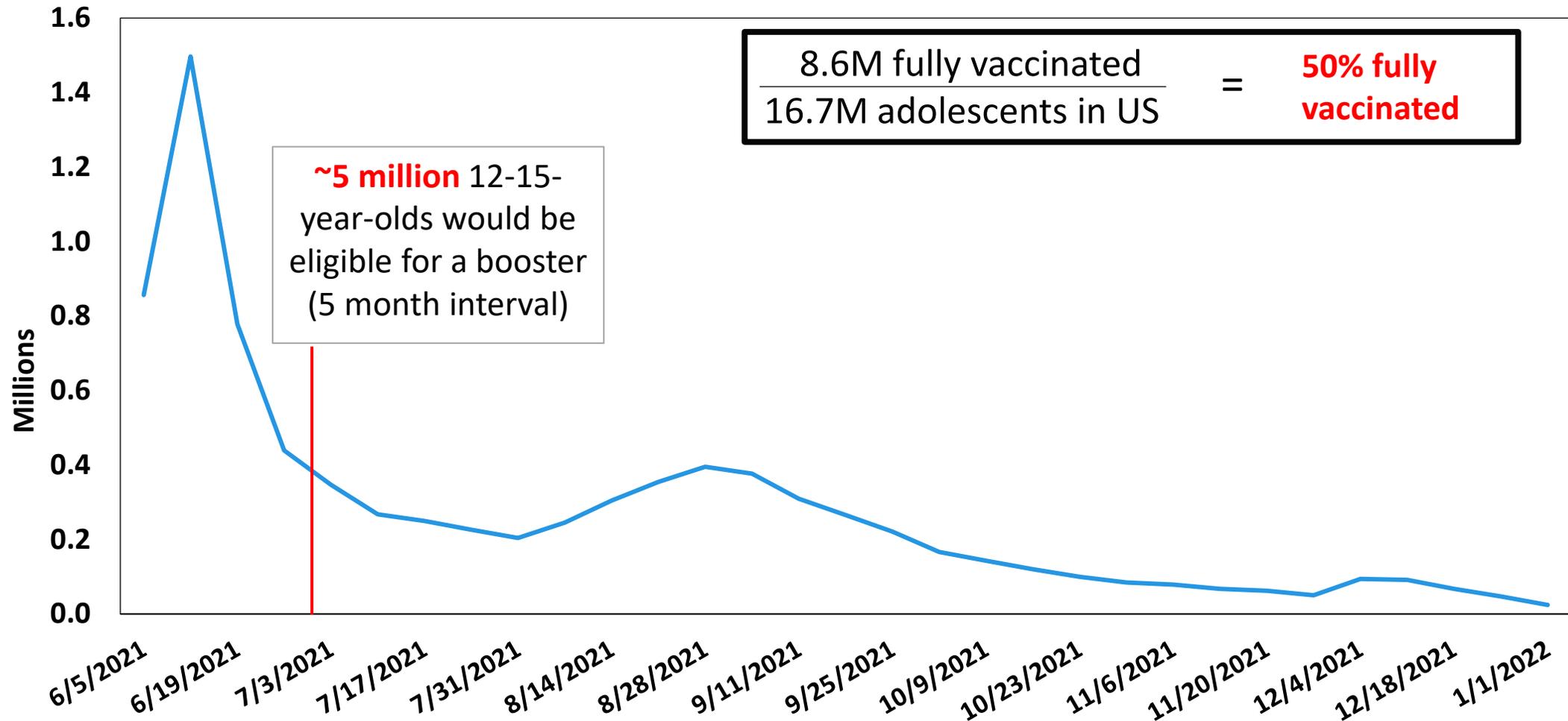
Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



Completed Primary Series among 12-15-Year-Olds by Week

June 5, 2021 – January 1, 2022

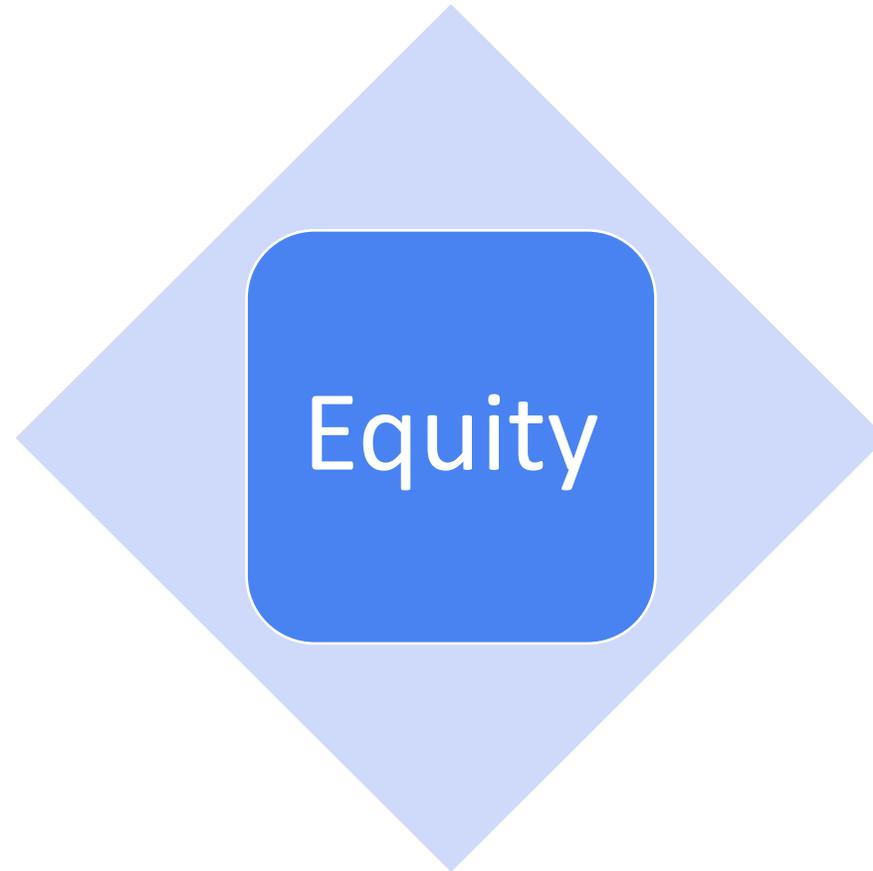


Feasibility of booster dose implementation in adolescents 12–15 years

- Half of the 12–15-year-old age group are fully vaccinated
- Based on booster experience with other age groups, 1/3 of adolescent 12–15 may return for a booster dose shortly after recommendation
- Supply of the Pfizer-BioNTech COVID-19 vaccine is robust, and the “gray cap” will be easier to distribute and administration
- Demand for pharmacy appointments is high; broadening eligibility could strain this further

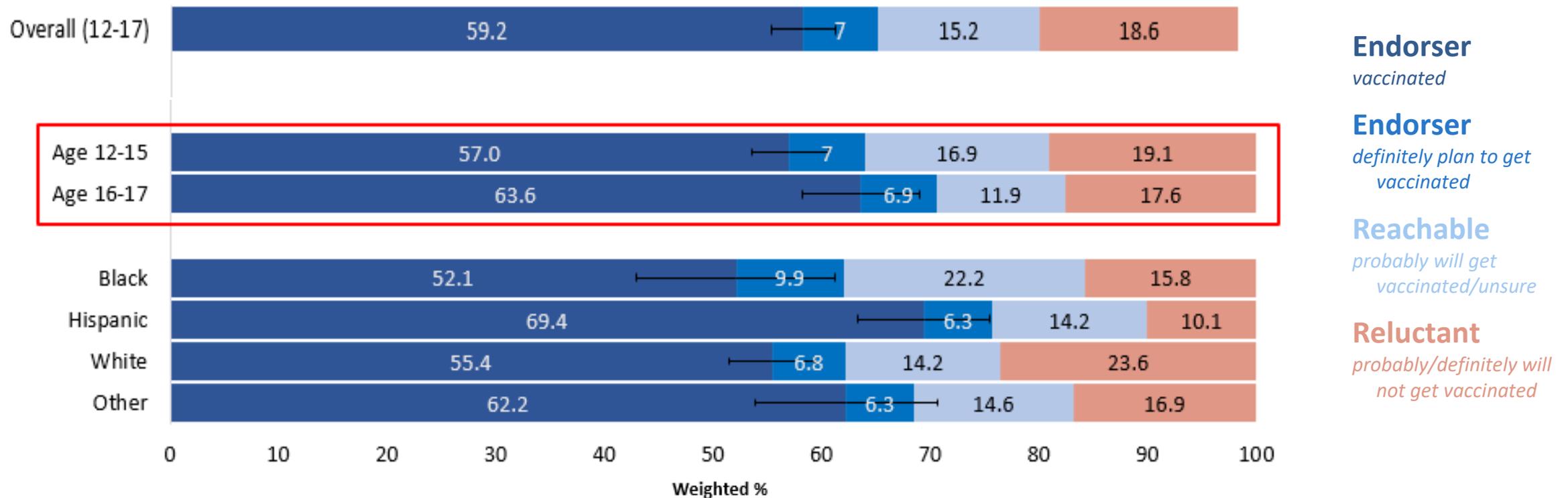
Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



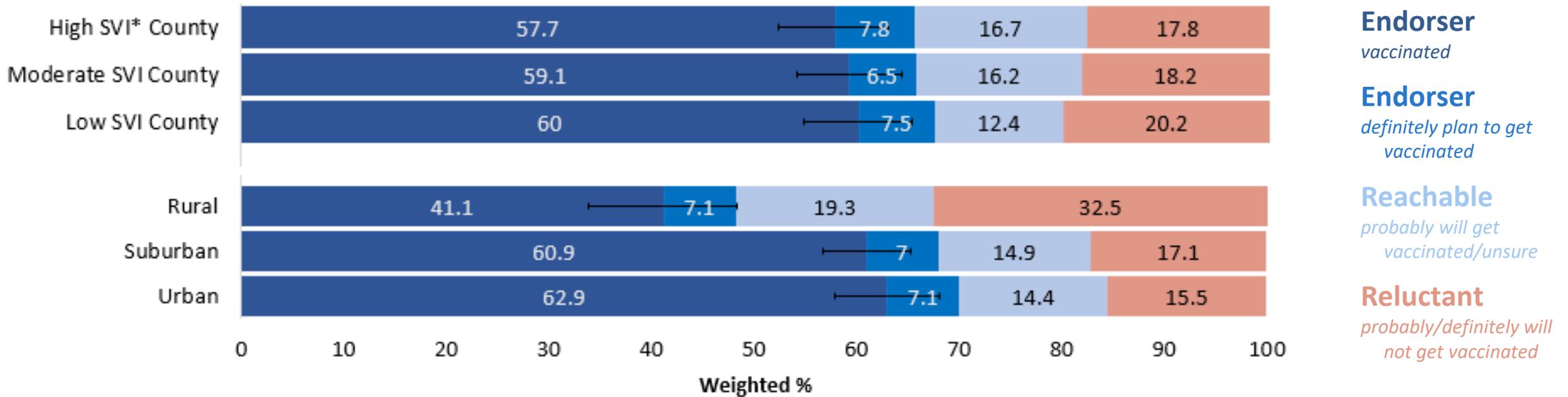
Vaccination coverage and parental intent for adolescents aged 12-17 years by race and ethnicity

NIS-CCM – Oct 31, 2021 – Nov 27, 2021, n=3,055



Vaccination coverage and parental intent for adolescents aged 12–17 years by county of residence SVI* and urbanicity

NIS-CCM – Oct 31, 2021 – Nov 27, 2021, n=3,055



*Social Vulnerability Index

Summary

- There are noted disparities in vaccination coverage and parental intent for children aged 12–17 years by **race/ethnicity** and **geographic location**

Summary



VaST assessment: Pfizer-BioNTech COVID-19 vaccine booster dose in 12–15-year-olds

- VaST reviewed the most recent data from three U.S. safety monitoring systems*, including data on safety after the primary vaccination series in 12–15-year-olds and after booster doses in 16–24-year-olds (the youngest age group for which boosters were previously authorized)
- No new safety signals or concerns were identified
- At the present time, data do not suggest safety concerns regarding a Pfizer-BioNTech COVID-19 vaccine booster dose for 12–15-year-olds, beyond those previously identified in older age groups

*VAERS, v-safe, VSD

Work Group Interpretation

- Top priority remains **vaccination of unvaccinated individuals**
 - **Benefits** of COVID-19 vaccine primary series **outweigh risk** across all sex and age groups

Goals of COVID-19 vaccines:

- Primary goal: Prevention of **severe disease**
- Secondary goals:
 - Maintaining workforce and healthcare capacity
 - Reduce infection rates and risk of transmission
 - Greater confidence in in-person learning
 - Improved mental health with more social interactions
 - Prevention of post-COVID conditions

Work Group Interpretation

- Work Group **supported** use of boosters in adolescents 12–15 years of age
- Emphasized the importance of **clear** and **consistent** recommendations for all adolescents (12–17 years of age)
- Vaccine recommendations can be updated as needed, especially in rapidly evolving pandemic

Evidence to Recommendations Framework

Type of recommendation	We do not recommend the intervention	We recommend the intervention for individuals based on assessment of benefits and risks	We recommend the intervention
-------------------------------	--------------------------------------	---	-------------------------------



Used when the **risks** clearly outweigh the **benefits**

Used when there is diversity of the **benefits** and **risks**

Used when the **benefits** clearly outweigh the **risks**

Can allow flexibility across a population

MAY
receive a booster

SHOULD
receive a booster

Work Group Interpretation

- Work Group discussed recommendation that adolescents 12–15 years of age may receive a booster dose, based on individual benefit-risk
 - Acknowledges limited data directly on the impact of boosters in adolescent population
 - In current Omicron surge, provides recommendation for boosters in a population that could have waning immunity due to both time since primary series and Omicron variant
- Work Group also discussed possible advantages of a recommendation that adolescents 12–15 years of age should receive a booster dose
 - Difficulty in defining individual benefit-risk balance and how it varies across population can be difficult for vaccine providers to communicate
 - In current Omicron surge, prevention of infection may have larger benefits that are difficult to measure (e.g. population-level protection, school attendance)

Individual benefit-risk considerations for people who may receive a booster dose

- Potential **benefits** of booster dose
 - Reduced risk of SARS-CoV-2 infection, severe disease
 - May reduce transmission of SARS-CoV-2 to others
- Potential **risks** of booster dose
 - Rare risks of serious adverse events (e.g., myocarditis, pericarditis, TTS, GBS, anaphylaxis)
 - Common risks of transient local and systemic symptoms
- **Individual risk factors** for SARS-CoV-2 infection
 - Risk of exposure (occupational and institutional settings, e.g., healthcare workers, long term care settings)
 - Risk for infection (time since completion of primary series)
- **Individual impacts** of SARS-CoV-2 infection
 - Risk for severe infection (related to underlying conditions)
 - Risk associated with a person's circumstances (living with/caring for at-risk individuals or consequences of inability to meet obligations due to infection)

Policy Question

- Should individuals 12–15 years of age receive a Pfizer-BioNTech COVID-19 vaccine booster dose under the current Emergency Use Authorization, based on the balance of benefits and risks?

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- Anthony Fiore
- Stephen Hadler
- Valerie Morelli
- JoEllen Wolicki
- Elisha Hall
- Erin Ricketts
- Faisal Minhaj
- Heather Scobie
- VTF ACIP WG Team
- ACIP COVID-19 Vaccines Work Group
- Vaccine Task Force
- Epi Task Force
- Data Analytics and Visualization Task Force
- Respiratory Viruses Branch

Questions to ACIP

- What does ACIP think about recommendations for booster doses of COVID-19 vaccines in adolescents 12–15 years of age?
 - What are the ACIP thoughts about a “may” recommendation for boosters in this population?
 - What are the ACIP thoughts about a “should” recommendation for boosters in this population?

Current recommendations for COVID-19 vaccine booster doses

Age	Pfizer-BioNTech COVID-19 vaccine primary series	Moderna COVID-19 vaccine primary series	Janssen COVID-19 vaccine primary series
≥18 years	Should receive a booster <u>5 months</u> after receipt of primary series dose	Should receive a booster <u>6 months</u> after receipt of primary series dose	Should receive a booster <u>2 months</u> after receipt of primary series dose
16–17 years	May receive a booster <u>5 months</u> after receipt of primary series dose	Not authorized	Not authorized

ACIP Vote

Interim Recommendation

A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons aged **12–15 years** at least **5 months** after the primary series based on **individual benefit and risk**, under the FDA's Emergency Use Authorization

Proposed recommendations for COVID-19 vaccine booster doses

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ACIP Vote

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