

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases



Evidence to Recommendations Framework:

2023 – 2024 (Monovalent, XBB Containing) COVID-19 Vaccine

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ACIP Meeting

September 12, 2023

The background features a blue gradient with various hexagonal shapes in different shades of blue and white, some overlapping and some as outlines, creating a geometric pattern.

Evidence to Recommendations Framework

Evidence to Recommendations (EtR) Framework

- Structure to describe information considered in moving from **evidence** to ACIP vaccine **recommendations**
- Provide **transparency** around the impact of additional factors on deliberations when considering a recommendation



Evidence to Recommendations (EtR) Framework

EtR Domain	Question(s)
Public Health Problem	<ul style="list-style-type: none">• Is the problem of public health importance?
Benefits and Harms	<ul style="list-style-type: none">• How substantial are the desirable anticipated effects?• How substantial are the undesirable anticipated effects?• Do the desirable effects outweigh the undesirable effects?
Values	<ul style="list-style-type: none">• Does the target population feel the desirable effects are large relative to the undesirable effects?• Is there important variability in how patients value the outcome?
Acceptability	<ul style="list-style-type: none">• Is the intervention acceptable to key stakeholders?
Feasibility	<ul style="list-style-type: none">• Is the intervention feasible to implement?
Resource Use	<ul style="list-style-type: none">• Is the intervention a reasonable and efficient allocation of resources?
Equity	<ul style="list-style-type: none">• What would be the impact of the intervention on health equity?

Evidence to Recommendations (EtR) Framework

EtR Domain	Question(s)	Domain Equity Question(s)
Public Health Problem	<ul style="list-style-type: none"> Is the problem of public health importance? 	<ul style="list-style-type: none"> Does the problem impact all populations equally?
Benefits and Harms	<ul style="list-style-type: none"> How substantial are the desirable anticipated effects? How substantial are the undesirable anticipated effects? Do the desirable effects outweigh the undesirable effects? 	<ul style="list-style-type: none"> Are the desirable and undesirable anticipated effects demonstrated across all populations equally?
Values	<ul style="list-style-type: none"> Does the target population feel the desirable effects are large relative to the undesirable effects? Is there important variability in how patients value the outcome? 	<ul style="list-style-type: none"> Is there important variability in how patients or populations value the outcome?
Acceptability	<ul style="list-style-type: none"> Is the intervention acceptable to key stakeholders? 	<ul style="list-style-type: none"> Is the intervention equally acceptable across all populations?
Feasibility	<ul style="list-style-type: none"> Is the intervention feasible to implement? 	<ul style="list-style-type: none"> Is the intervention equally feasible to implement across all populations?
Resource Use	<ul style="list-style-type: none"> Is the intervention a reasonable and efficient allocation of resources? 	<ul style="list-style-type: none"> Is the intervention a reasonable and efficient allocation of resources across all populations?

The intervention = 2023 – 2024 (monovalent, XBB containing) COVID-19 vaccine
 The problem = COVID-19

Evidence to Recommendations (EtR) Framework

Policy Question

- Should 2023 - 2024 (monovalent, XBB containing) COVID-19 vaccines authorized under EUA or approved by BLA be recommended for use in persons ≥ 6 months of age?

Products and ages currently authorized or approved by FDA include:

- Moderna COVID-19 vaccine for ages 6 months and older
- Pfizer-BioNTech COVID-19 vaccine for ages 6 months and older

Products and ages under review for authorization or approval by FDA include:

- Novavax COVID-19 vaccine for ages 12 years and older

Bivalent COVID-19 vaccine recommendations for mRNA COVID-19 vaccines

Unvaccinated

2 doses
Moderna

OR

3 doses
Pfizer-
BioNTech

6 months – 4/5 years

1 dose
Moderna

OR

1 dose
Pfizer-
BioNTech

≥5/6 years

Previously vaccinated

1 dose
Moderna

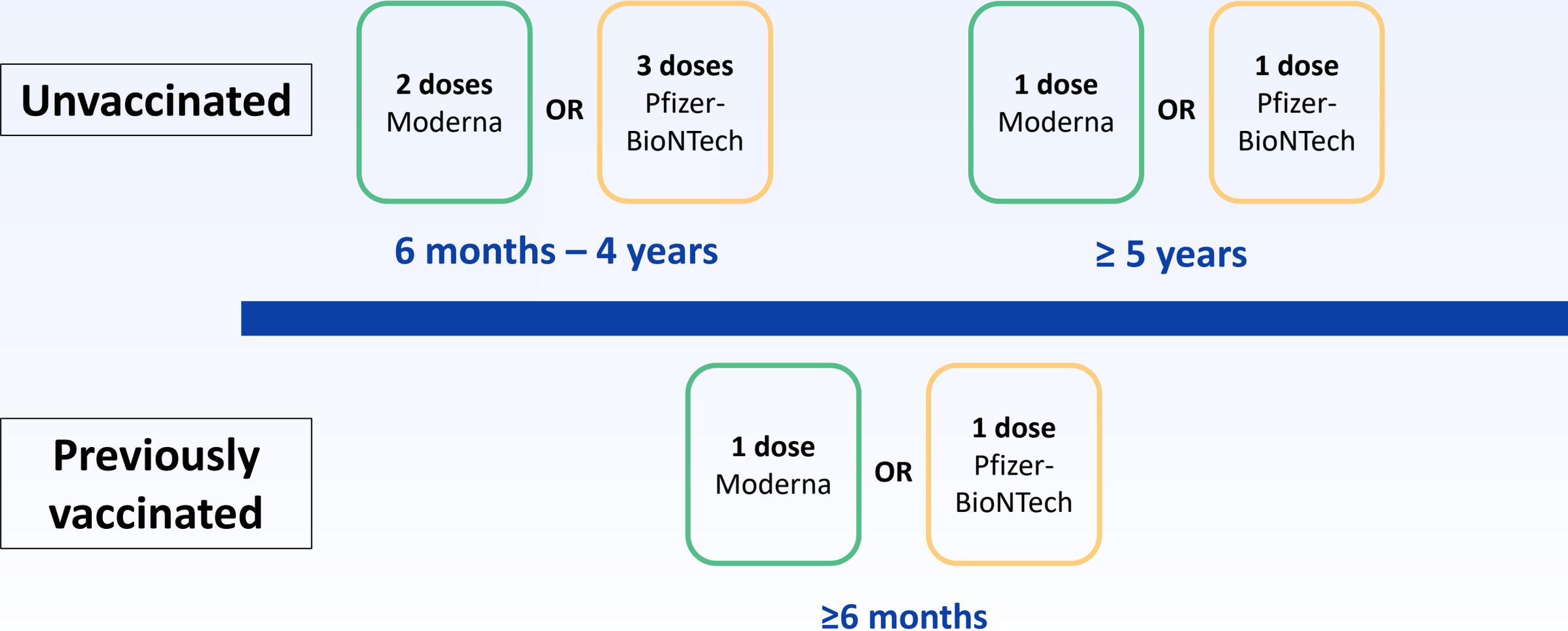
OR

1 dose
Pfizer-
BioNTech

≥6 months

Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

Proposed 2023 – 2024 COVID-19 vaccine recommendations for mRNA COVID-19 vaccines



Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

Current recommendations for Novavax COVID-19 vaccine

- The **original Novavax COVID-19** vaccine remains authorized for use as a 2-dose primary series
- The **original Novavax COVID-19** vaccine can be given as booster dose in limited situations to
 - People ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine
 - Have not received any previous booster dose(s)
 - Are unable (i.e., mRNA vaccine contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose
- Authorizations or approvals for **2023 – 2024 Novavax COVID-19 vaccine** will be determined by FDA with CDC recommendations to follow

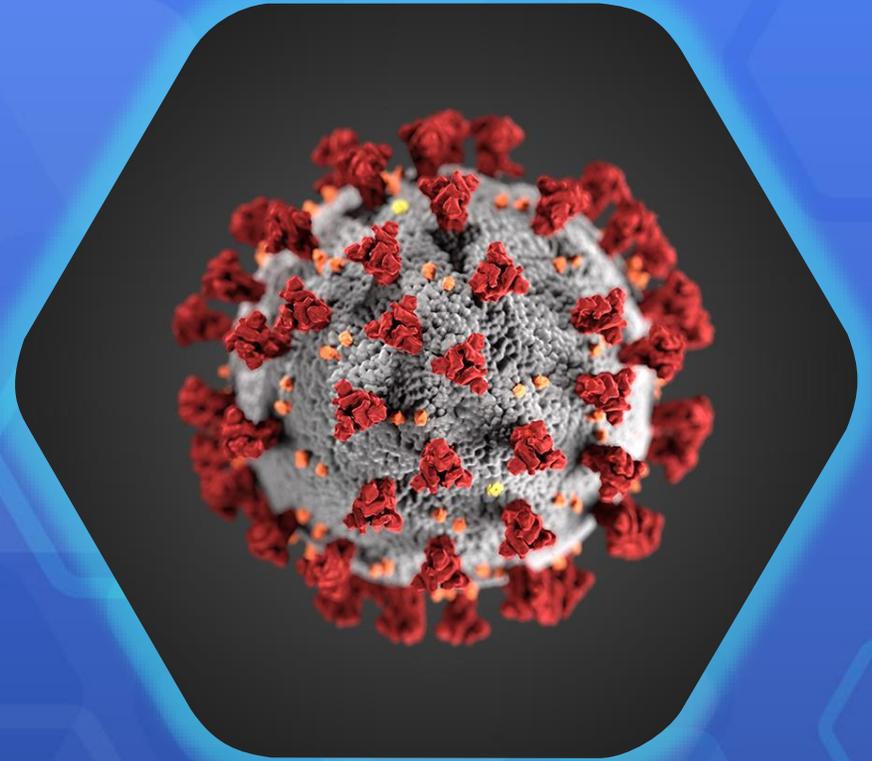
COVID-19 vaccine nomenclature

- Updated COVID-19 vaccine referred to as the “2023–2024 COVID-19 vaccine” in this presentation
- Following ACIP meeting, both “updated COVID-19 vaccine” and “2023–2024 COVID-19 vaccine” will be used to refer to the monovalent XBB.1.5 containing vaccines

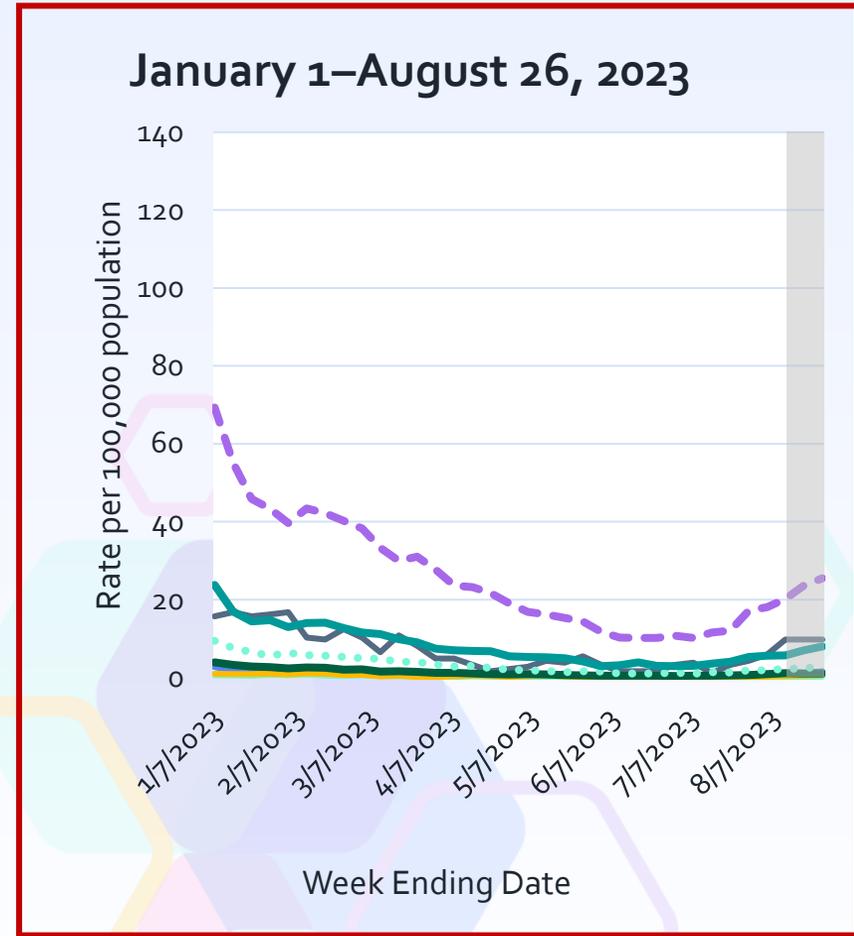
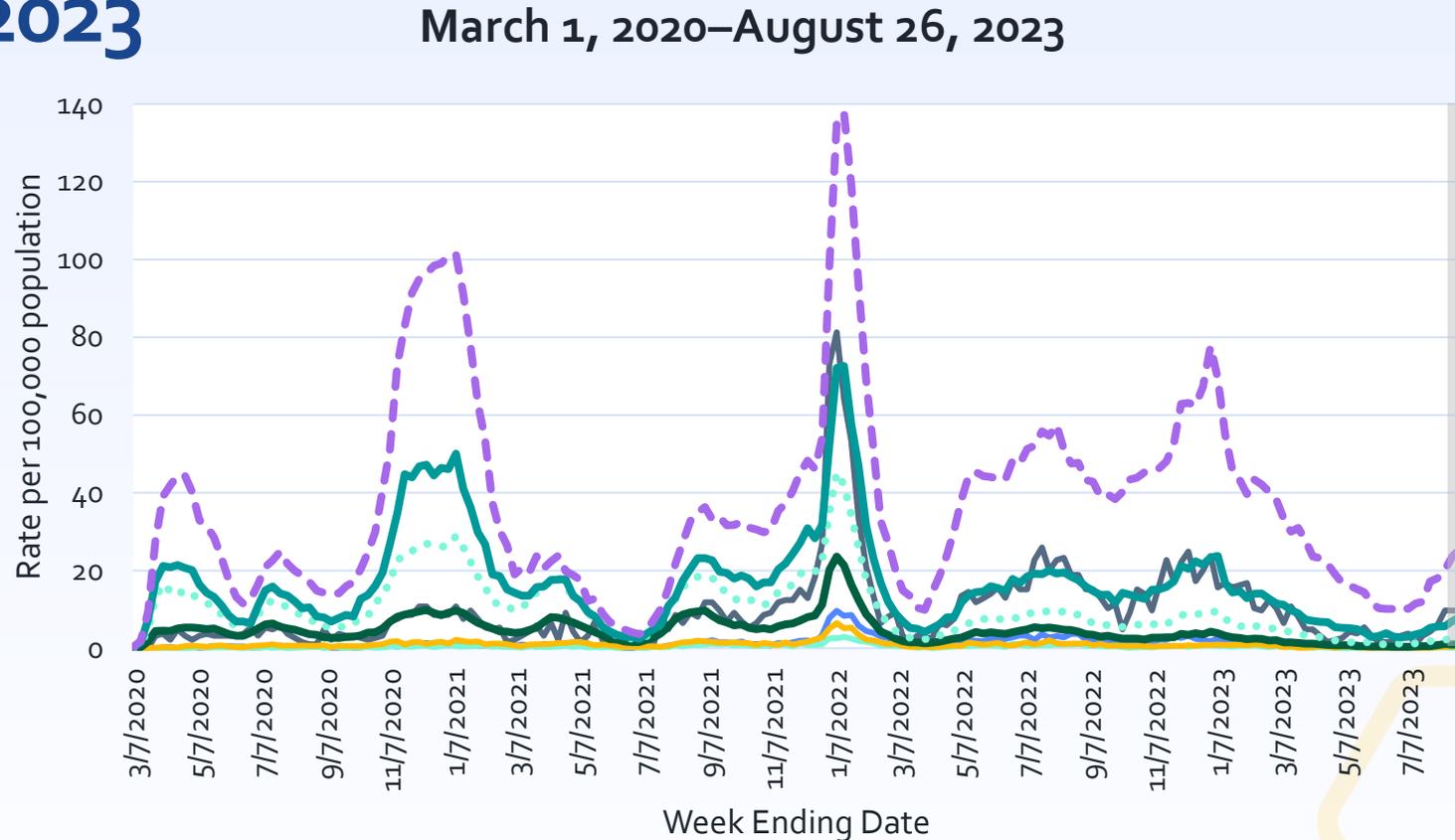


EtR Domain:

Public Health Problem



Weekly Population-Based Rates of COVID-19-Associated Hospitalizations — COVID-NET, March 2020–August 26, 2023



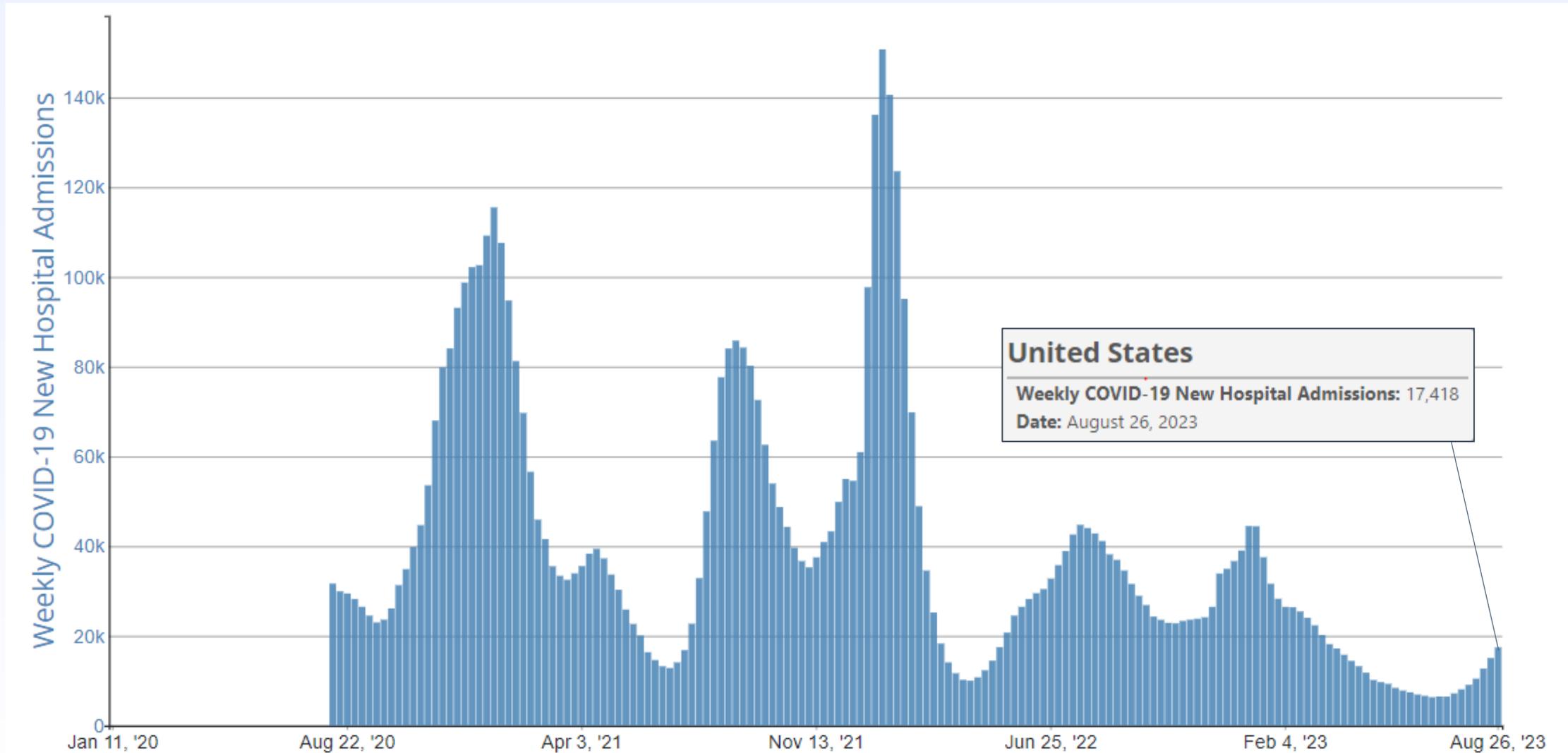
- <6 months
- 6 months–4 years
- 5–11 years
- 12–17 years
- 18–49 years
- 50–64 years
- 65–74 years
- ≥75 years

Rates highest in ≥75 years, followed by infants <6 months and adults 65–74 years

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

COVID-19 new hospital admissions, by week, in the United States

National Healthcare Safety Network (NHSN), August 2020 – August 2023



Source: COVID-19-associated hospitalization data reported to CDC's National Healthcare Safety Network (NHSN).

https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00

Other pediatric vaccine preventable diseases: Annual hospitalizations per 100,000 population prior to recommended vaccines compared to COVID-19

	Hepatitis A ¹	Varicella ² (Chickenpox)	Vaccine-type Invasive Pneumococcal Disease ³	COVID-19 ⁴
Age	5–14 years	0–4 years	0–4 years	6 months–<18 years
Time period	2005	1993–1995	1998–1999	2021–2022 2022–2023
Hospitalization Burden (Annual rate per 100,000 population)	<1	29-42	40 ⁵	≤4 years: 92–220 5–11 years: 15–47 12–17 years: 20–80

¹ <https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm>

² Davis MM, Patel MS, Gebremariam A. Decline in varicella-related hospitalizations and expenditures for children and adults after introduction of varicella vaccine in the United States. *Pediatrics*. 2004;114(3):786-792. doi:10.1542/peds.2004-0012

³ Centers for Disease Control and Prevention (CDC). Direct and indirect effects of routine vaccination of children with 7-valent pneumococcal conjugate vaccine on incidence of invasive pneumococcal disease--United States, 1998-2003. *MMWR Morb Mortal Wkly Rep*. 2005 Sep 16;54(36):893-7. PMID: 16163262.

⁴ COVID-NET data October 2021 – September 2022 and October 2022 – July 2023. COVID-19 rates have not been adjusted for reason for admission. COVID vaccine first introduced in 12-17 years in May 2021; in 5-11 years in November 2021 and in 6 months – 4 years in June 2022

COVID-19 Scenario Modeling Hub

- A multi-team effort aimed at creating and modeling planning scenarios of the mid- to long-term COVID-19 situation
- Scenarios developed in close collaboration with government agencies and other stakeholders
- Project hospitalizations and deaths

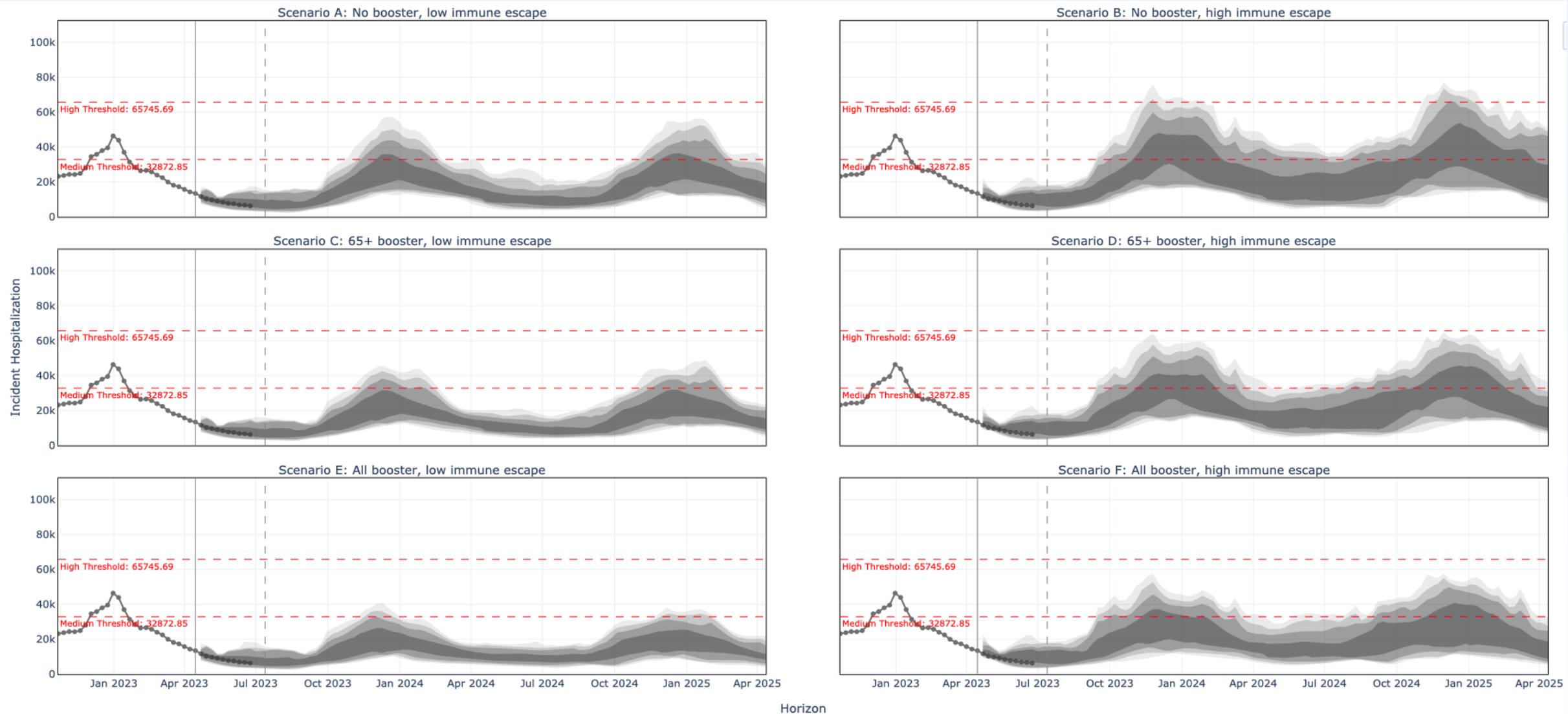


Assumptions of COVID-19 Scenario Modeling Hub Round 17

- **Six** scenarios focusing on three vaccine recommendation scenarios and two different rates of immune escape
 - **No vaccine recommendation vs recommendation for 65+ years vs universal recommendation**
 - **Low** immune escape vs **high** immune escape¹
- Assumed vaccines reformulated to target strains circulating on June 15th of each year, made available September 1
- Reformulated vaccines assumed to have **65% VE against symptomatic infection** with the **strain targeted by reformulation**
- Vaccine uptake based on **first booster uptake** (September 2021)
- Teams required to **project a minimum of 2 years** into the future
- Eight teams provided national level projections

1. Low immune escape: immune escape occurs at a constant rate of 20% per year; high immune escape: immune escape occurs at a constant rate of 50% per year

Based on ensemble projections, weekly hospitalizations are likely to increase this winter and stay within last year's range



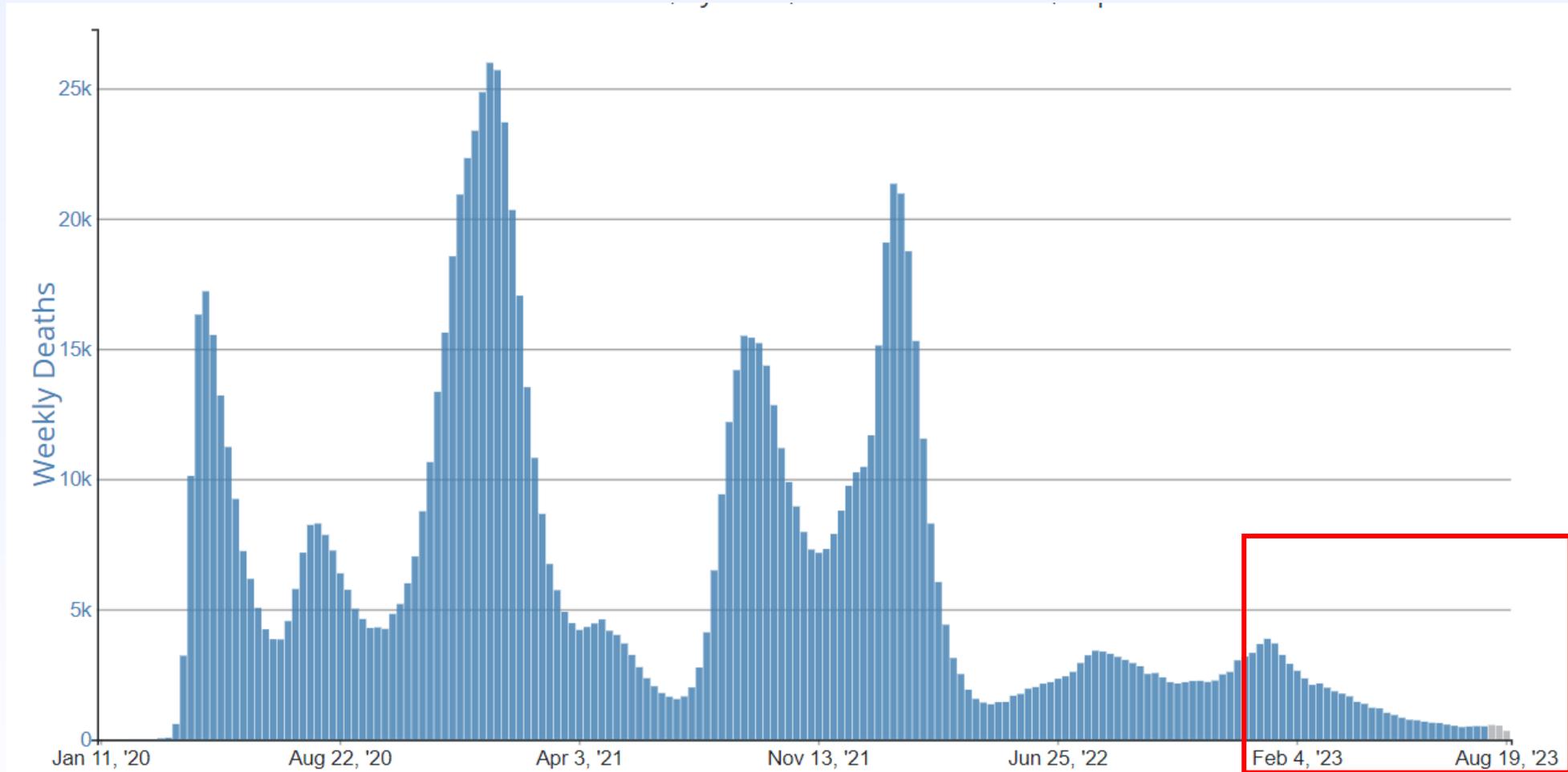
People ages 6 months – 49 years with no underlying conditions are still admitted to the ICU with COVID-19

COVID-NET: Underlying Medical Conditions among Patients Admitted to ICU among Children, Adolescents, and Adults Ages 6 Months – 49 Years, July 2022–June 2023

Age category	% with no underlying conditions	Of those with no underlying conditions, what % were admitted to ICU?	% admitted to ICU with no underlying conditions
6–23 months	57%	27%	53%
2–4 years	39%	19%	32%
5–11 years	24%	23%	24%
12–17 years	25%	31%	22%
18–49 years	16%	15%	13%

- Relative standard errors >30%; estimates might be unstable due to small sample size
- Limited to COVID-NET hospitalizations with COVID-19-related illness as likely reason for admission

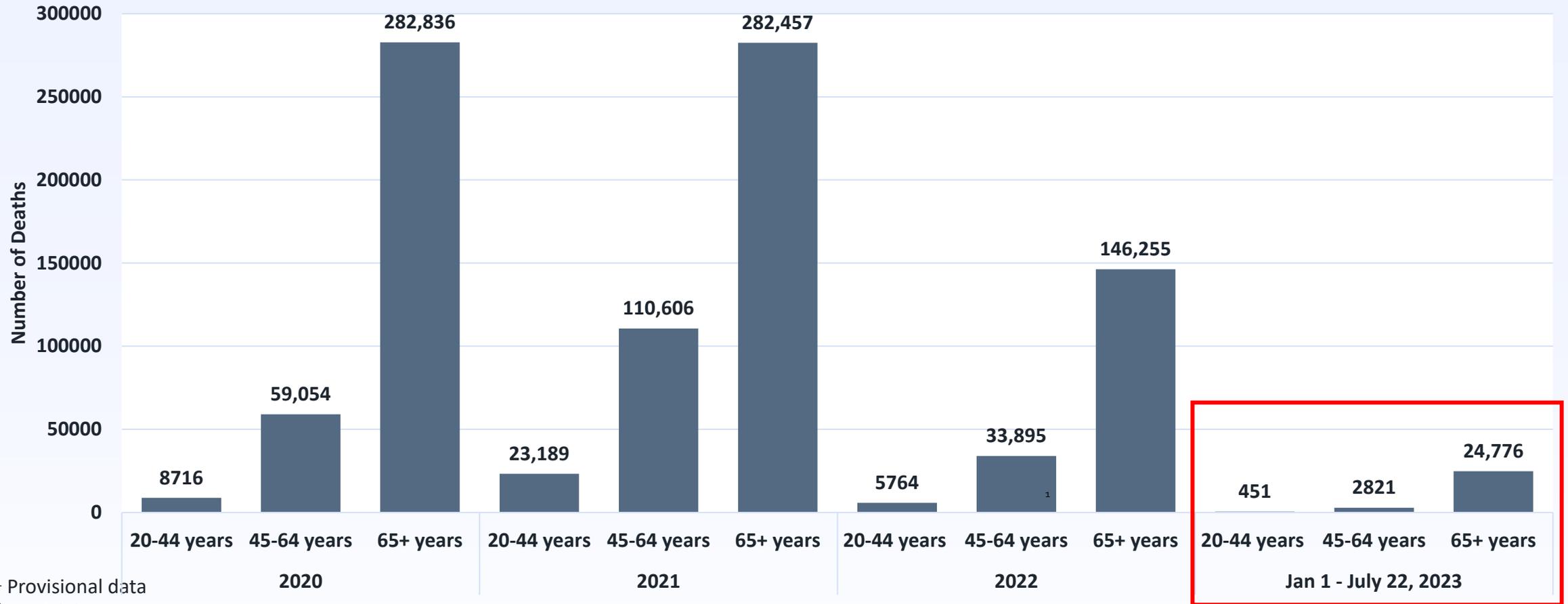
Provisional COVID-19 deaths, by week, in the United States, reported to CDC



The most recent 3 weeks of mortality counts are shaded grey because NVSS reporting is <95% during this period.

Source: Provisional Deaths from the CDC's National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS). https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_weeklydeathrateaa_00

COVID-19-associated deaths in persons ages ≥20 years (by underlying cause of death), by age group and year – National Vital Statistics System

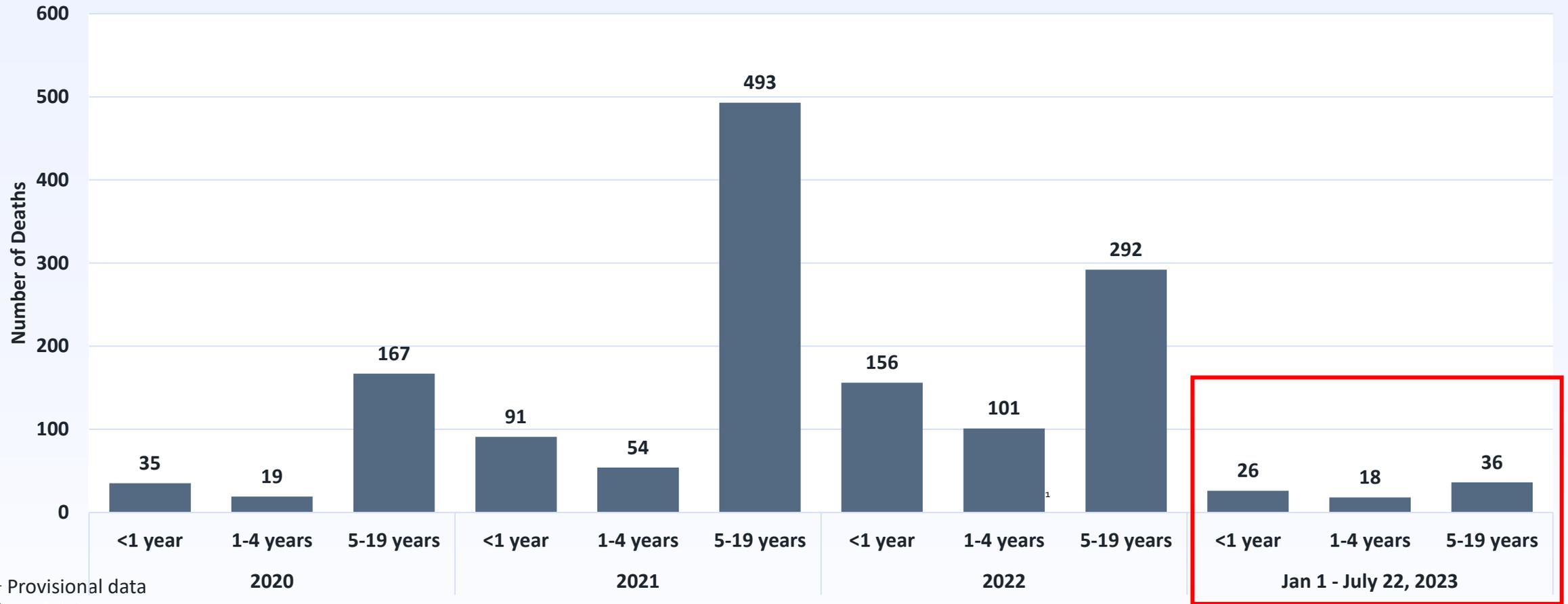


¹ Provisional data

² Partial data

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2023, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes COVID-19 code (U07.1) as the underlying cause of death. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on Aug 25, 2023 4:53:59 PM

COVID-19-associated deaths in persons ages ≤19 years (by underlying cause of death), by age group and year – National Vital Statistics System



¹ Provisional data

² Partial data

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2023, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes influenza codes (J09-J11) or COVID-19 code (U07.1) as the underlying cause of death. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on Aug 25, 2023 4:53:59 PM

Among children ≤17 years who died in-hospital, 50% had no underlying conditions

COVID-NET: Underlying Medical Conditions among Patients with In-Hospital Death among Children and Adolescents Ages ≤17 Years, January 2022–June 2023

Age category	% with no underlying conditions	Of those with no underlying conditions, what % died in-hospital?	% of those who died in-hospital with no underlying conditions
≤17 years	51%	1%*	50%

Limited to COVID-NET hospitalizations with COVID-19-related illness as likely reason for admission

* Relative standard error >30; indicates estimate might be unstable due to low sample size (n=24).

Pediatric vaccine preventable diseases: Deaths per year in the United States prior to recommended vaccines compared to COVID-19

	Hepatitis A ¹	Meningococcal (ACWY) ²	Varicella ³	Rubella ⁴	Rotavirus ⁵	COVID-19 ⁶
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months–<18 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	2022
Average deaths per year	3	8	16	17	20	≤1 year: 156 1–4 years: 101 5–19 years:292

¹Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8.

²National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019.

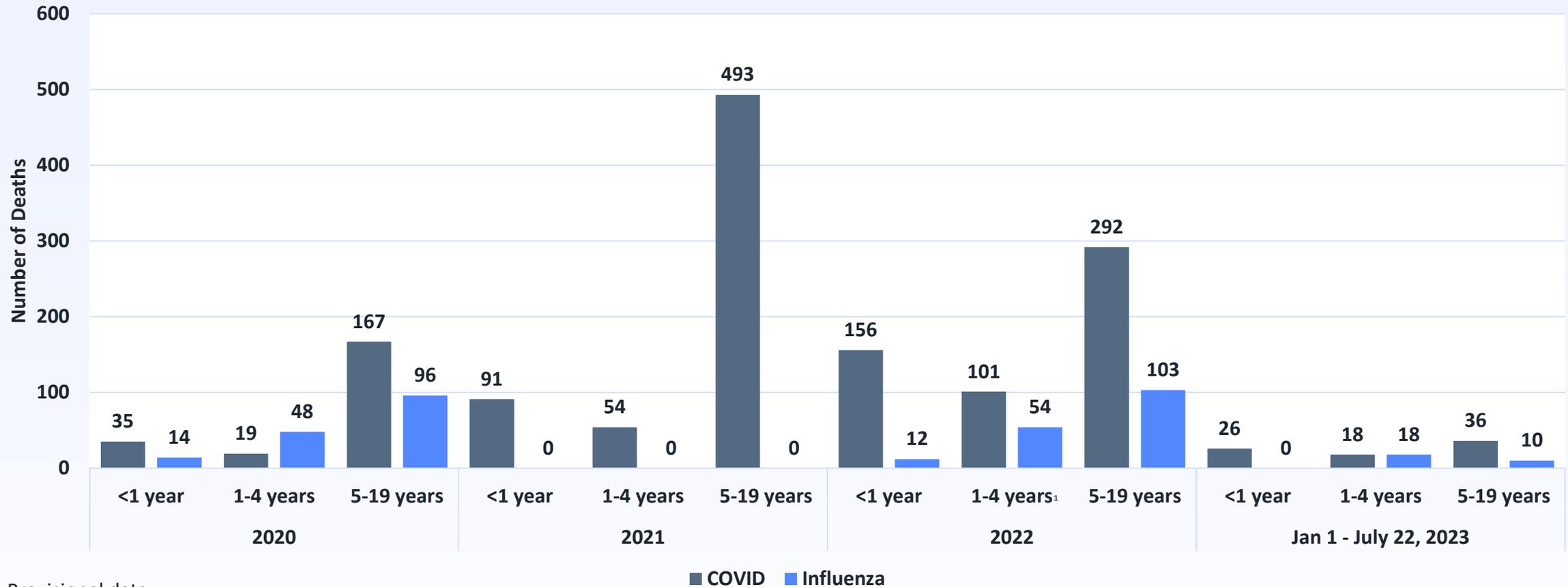
³Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. J Infect Dis. 2000;182(2):383-390. doi:10.1086/315714

⁴Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63.

⁵Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5-11

⁶<http://wonder.cdc.gov/mcd-icd10-provisional.html> on Aug 1, 2023 . COVID vaccine first introduced in 12-17 years in May 2021; in 5-11 years in November 2021 and in 6 months – 4 23 years in June 2022

COVID-19 and Influenza -associated deaths in persons ages ≤19 years (by underlying cause of death), by age group and year – National Vital Statistics System



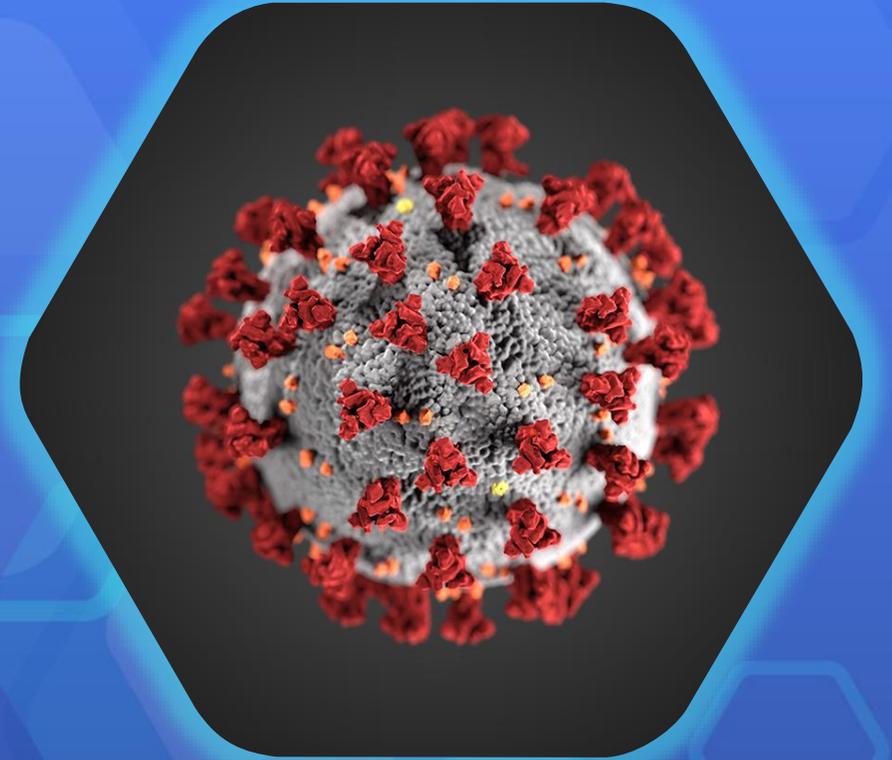
¹ Provisional data

² Partial data

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2023, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes influenza codes (J09-J11) or COVID-19 code (U07.1) as the underlying cause of death. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on Aug 25, 2023 4:53:59 PM

Domain Equity Question:

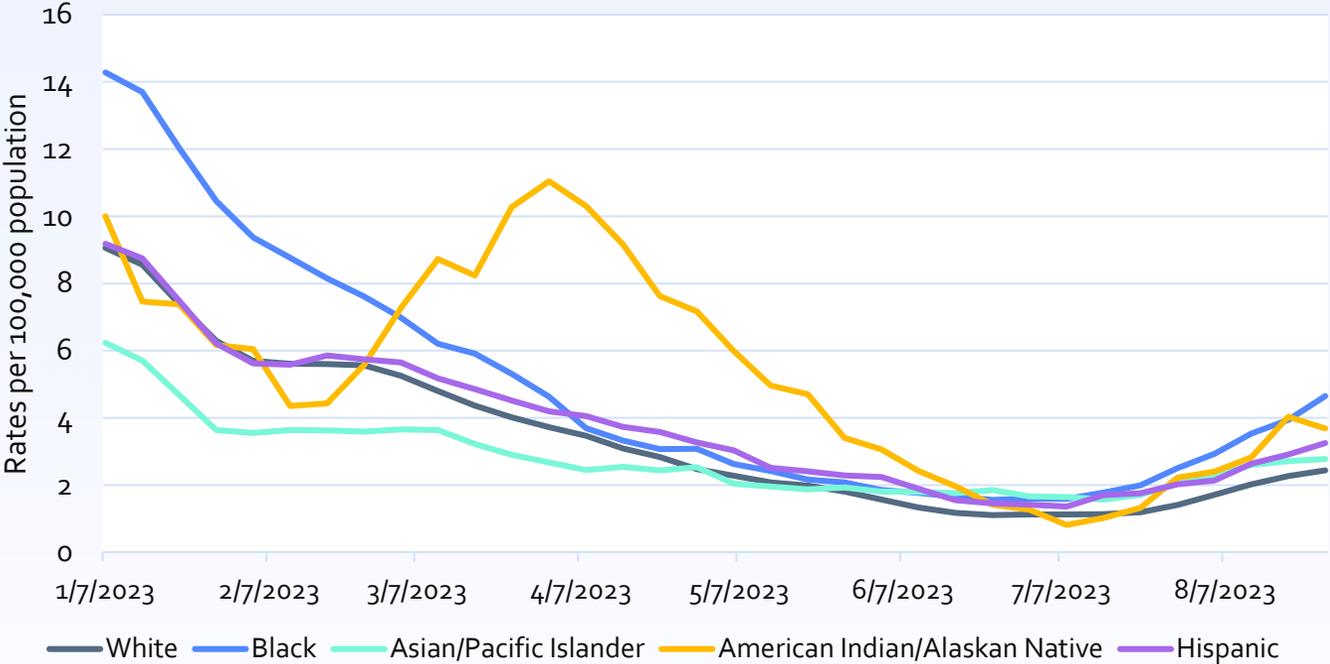
Does the problem impact all populations equally?



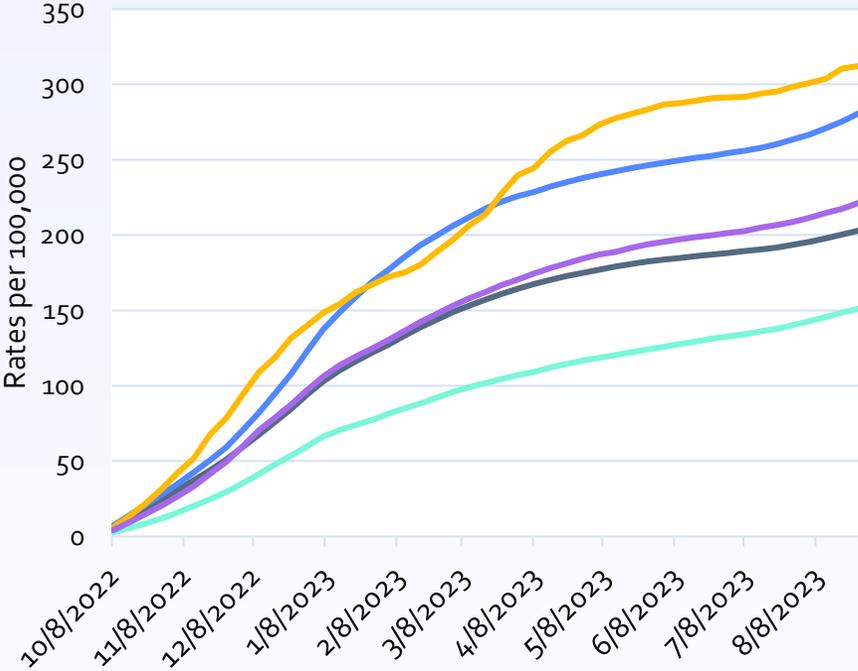
Age-adjusted COVID-19-associated hospitalization rates by race and ethnicity* — COVID-NET, October 2022 – August 2023

2023

3-week moving average rate
January – August 2023



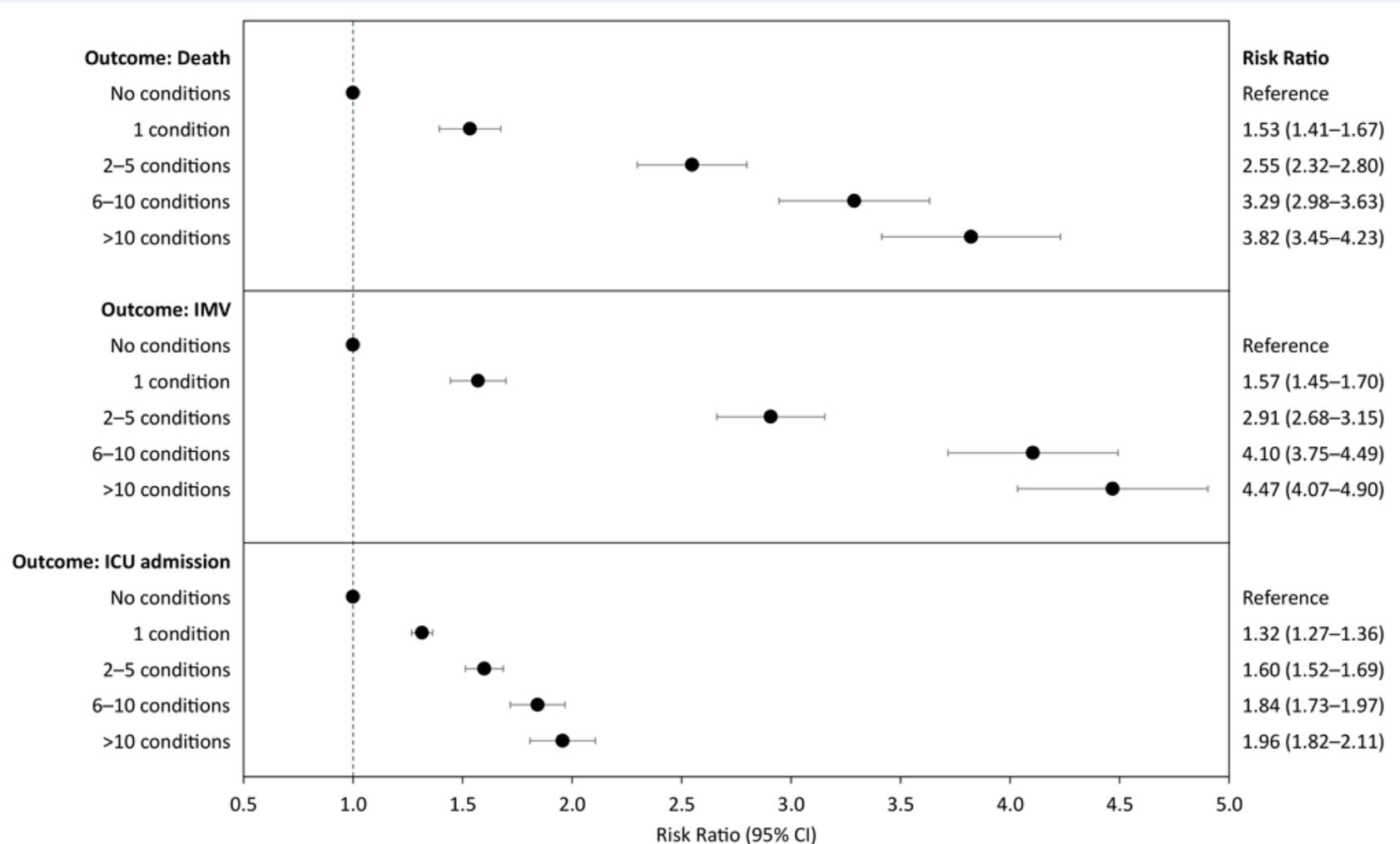
Cumulative rates
October 2022 – August 2023



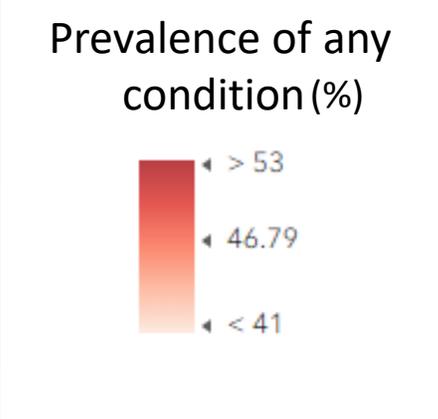
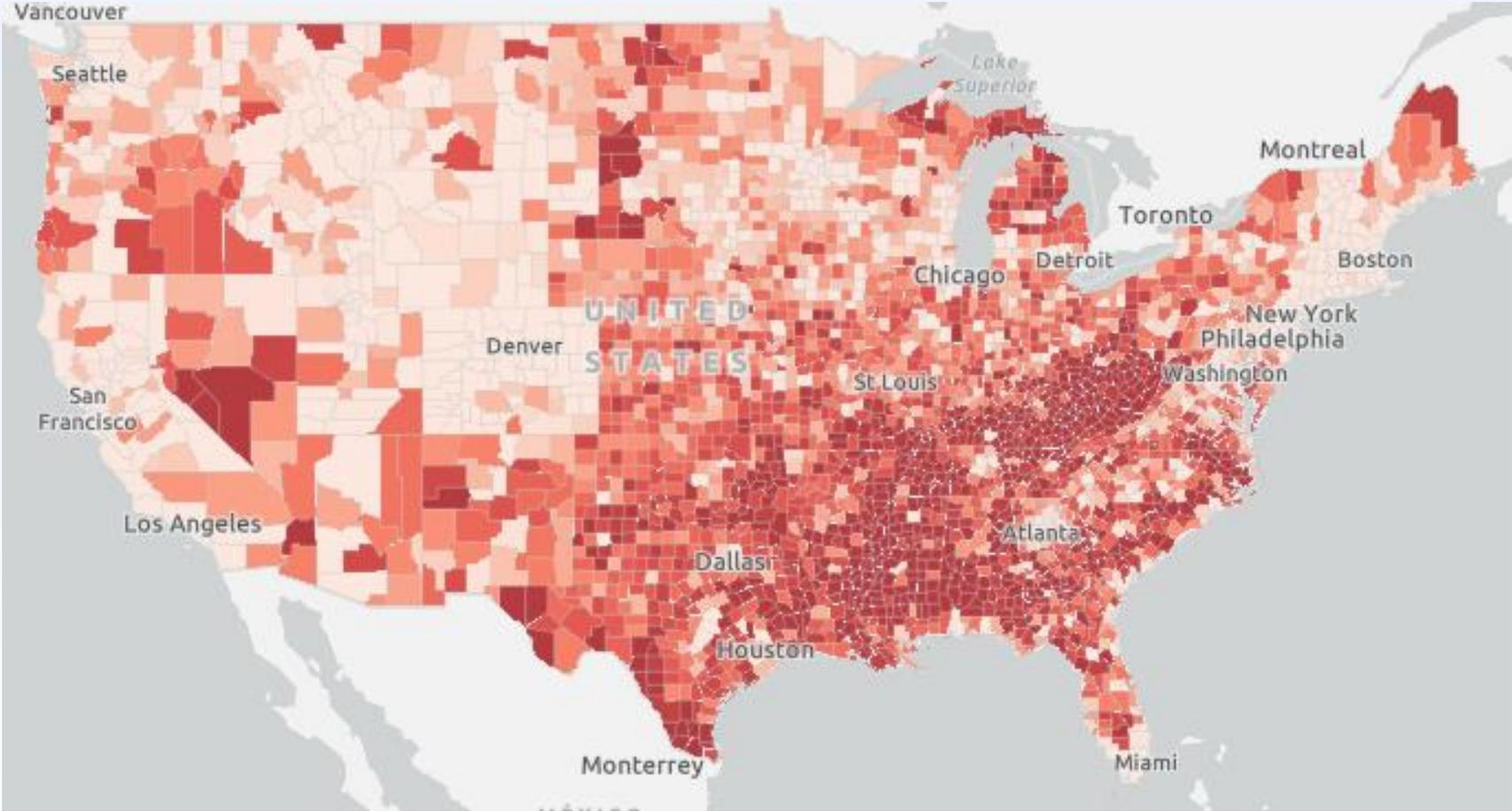
Cumulative hospitalization rates remain highest in American Indian/Alaska Native and Black persons

* Black, White, American Indian/Alaska Native and Asian/Pacific Islander people were categorized as non-Hispanic; Hispanic people could be of any race.

Risk ratio of death, invasive mechanical ventilation (IMV), and admission to intensive care unit (ICU), by the number of underlying medical conditions among adults hospitalized with COVID-19, March 2020–March 2021

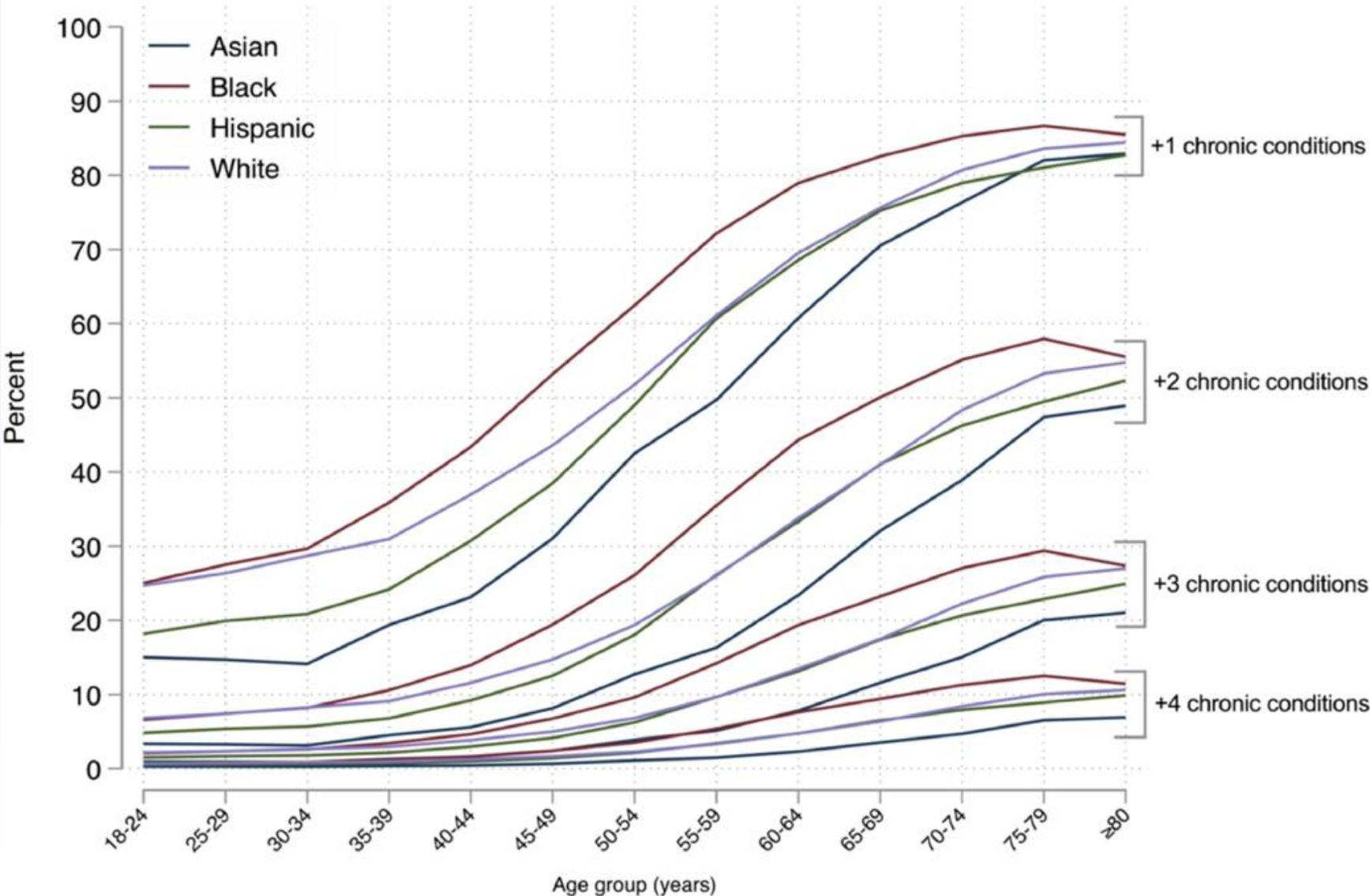


Selected chronic conditions by U.S. county, 2018



Based on Razzaghi H, Wang Y, Lu H, Marshall KE, Dowling NF, Paz-Bailey G, Twentymen ER, Peacock G, Greenlund KJ, Estimated County-Level Prevalence of Selected Underlying Medical Conditions Associated with Increased Risk for Severe COVID-19 Illness - United States, 2018 MMWR Morb Mortal Wkly Rep 2020;69[945-950]. The underlying medical conditions included in these prevalence estimates were selected using a subset of the list of conditions with the strongest and most consistent evidence of association with increased risk for severe COVID-19-associated illness on CDC's website as of June 25, 2020 and for which questions on the BRFSS are available. <https://covid.cdc.gov/covid-data-tracker/#underlying-med-conditions>

Number of chronic conditions by age among Asian, Black, Latino/Hispanic, and White adults in the National Health Interview Survey, 1999 to 2018



Source: Caraballo C, Herrin J, Mahajan S, et al. Temporal Trends in Racial and Ethnic Disparities in Multimorbidity Prevalence in the United States, 1999-2018. *Am J Med.* 2022;135(9):1083-1092.e14. doi:10.1016/j.amjmed.2022.04.010

Summary

Public Health Problem

- COVID-19 burden is **currently lower** than at previous points in the pandemic, however the **absolute number** of hospitalizations and deaths is still **high**
- Although hospitalization rates are currently low in some age groups, we have seen rates increase in recent weeks and **anticipate further increases** as we enter respiratory virus season
- Infants and older adults have the **highest** COVID-19-associated hospitalization rates
- Children and adults with **no underlying medical conditions** still experience severe illness due to COVID-19
- Post-COVID Conditions are **common** following SARS-CoV-2 infection, decrease with time since infection, and have decreased since the start of the pandemic
- People of racial and ethnic minority groups continue to be **disproportionately impacted** by COVID-19
- High proportions of underlying conditions may put certain groups at **increased risk** for severe outcomes due to COVID-19

Public Health Problem

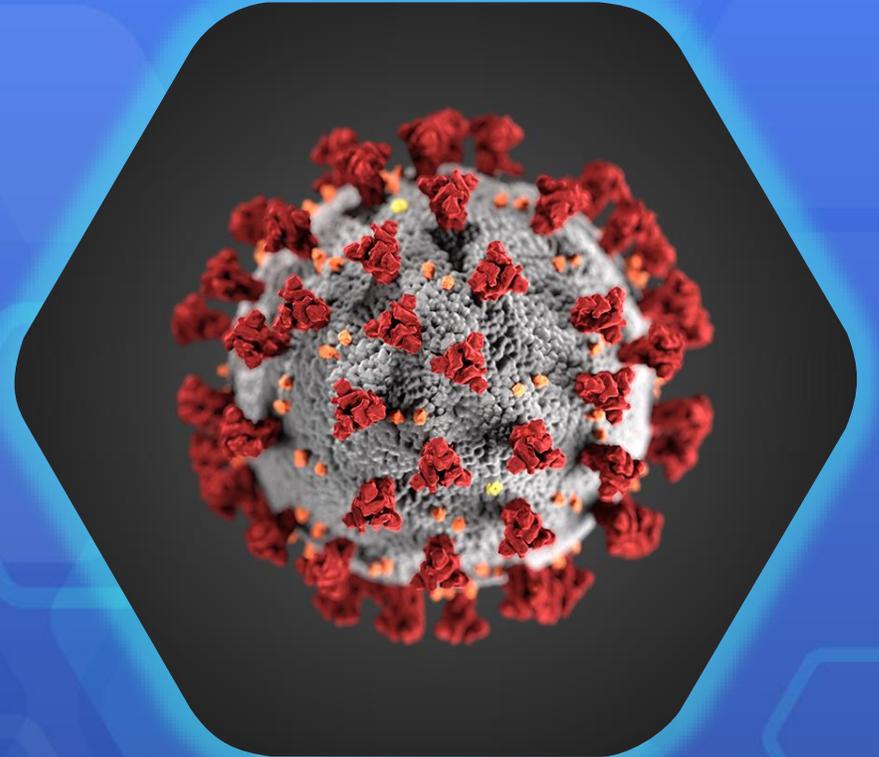
Work Group Interpretation

Is COVID-19 disease among persons \geq 6 months of public health importance?

- No Probably no Probably yes Yes Varies Don't know

EtR Domain:

Benefits and Harms



Summary of available data

- Data from COVID-19 vaccine manufacturers
 - Moderna monovalent XBB.1.5 containing vaccine clinical trial data
 - Novavax monovalent XBB.1.5 containing preclinical data
 - Pfizer-BioNTech monovalent XBB.1.5 containing preclinical data
- GRADE
 - Benefits and harms of an updated COVID-19 vaccine
- Post-authorization safety and effectiveness monitoring
 - Vaccine Safety Datalink and other vaccine safety monitoring systems
 - CDC vaccine effectiveness platforms
- Additional considerations
 - Benefit-risk assessment
 - Modeling data



Available data from COVID-19 vaccine manufacturers

▪ Moderna

– Clinical trial data

- Randomized 101 patients to monovalent XBB.1.5 containing dose or bivalent BA.4/5 + XBB.1.5 containing dose
- Patients that received the monovalent XBB.1.5 containing dose demonstrated an increase in neutralizing antibodies, with similar levels of neutralization across several XBB sub-variants
- Reported reactogenicity was similar to or lower than that reported from previous doses

▪ Novavax

– Preclinical data

- Macaques boosted with XBB.1.5 demonstrated increased neutralizing response across several XBB pseudoviruses

▪ Pfizer-BioNTech

– Preclinical data

- Mice boosted with XBB.1.5 demonstrated increased neutralizing response across several XBB pseudoviruses

GRADE

- GRADE approach was applied to assess the type and quality of evidence for the anticipated benefits and harms of an updated COVID-19 vaccine
- The PICO question and inclusion/exclusion criteria were intentionally narrow to best capture evidence most applicable to what can be anticipated from this year's vaccine dose in the U.S., including limiting evidence to U.S. studies of an updated vaccine formulation (i.e., bivalent mRNA vaccine)
- Two separate PICO questions were evaluated based on dosing cut-offs
- These narrow criteria reduced the number of studies available in the body of evidence, however this GRADE assessment builds upon a large body of evidence from the original monovalent vaccines

PICO Question – Adolescents and Adults

Population	Persons ages 12 years and older
Intervention	Updated mRNA COVID-19 vaccine
Comparison	No updated vaccine
Outcomes	Medically-attended COVID-19 (ED/UC visits) Hospitalization due to COVID-19 Death due to COVID-19 Post-COVID Conditions Specified Serious Adverse Events Reactogenicity

PICO Question - Infants and Children

Population	Persons ages 6 months – 11 years
Intervention	Updated COVID-19 mRNA vaccine
Comparison	No updated vaccine
Outcomes	Medically-attended COVID-19 (ED/UC visits) Hospitalization due to COVID-19 Death due to COVID-19 MIS-C Post-COVID Conditions Specified Serious Adverse Events Reactogenicity

Outcomes, Importance, and Data Sources

Outcome	Importance ^a	Data sources
Benefits		
Medically-attended COVID-19 (ED/UC visits)	Critical	Observational studies of vaccine effectiveness
Hospitalization due to COVID-19	Critical	Observational studies of vaccine effectiveness
Death due to COVID-19	Important	Observational studies of vaccine effectiveness
MIS-C – <i>pediatrics only</i>	Important	Observational studies of vaccine effectiveness
Post-COVID Conditions	Important	Observational studies of vaccine effectiveness
Harms		
Specified serious adverse events (SAEs)	Critical	Safety surveillance for specified SAEs
Reactogenicity	Important	RCTs for monovalent doses

^a Three options: Critical; Important but not critical; Not important for decision making

Evidence Retrieval

- **Observational Studies for Benefits (Vaccine Effectiveness)**
 - *Published or preprint* articles from International Vaccine Access Center (IVAC) systematic review^a
 - Restricted to PICO defined population, intervention, comparison, and outcome
- **Safety Surveillance for Serious Adverse Events**
 - Data on safety signals identified by vaccine safety surveillance systems
 - Based on input from CDC Immunization Safety Office (ISO)
- **Randomized Controlled Trials (RCTs) for Reactogenicity**
 - Data on reactogenicity identified by relevant phase 1, 2, or 3 RCTs from clinicaltrials.gov
 - Unpublished data from vaccine manufacturers

^a Articles were eligible for inclusion if *published or uploaded to a preprint* server before 6/29/2023;

Observational Data (n = 6)

- 6 records identified (one or more PICO outcomes)
- Assessed risk of bias using Newcastle-Ottawa Scale (9-point scale)
 - For cohort studies: **Selection** of cohorts, **Comparability** of cohorts, **Assessment** of outcome
 - For case-control or test-negative design studies: **Selection** of cases and controls, **Comparability** of cases and controls, **Ascertainment** of exposure
- Two reviewers assessed each study for each outcome
- Serious limitations identified by score <7

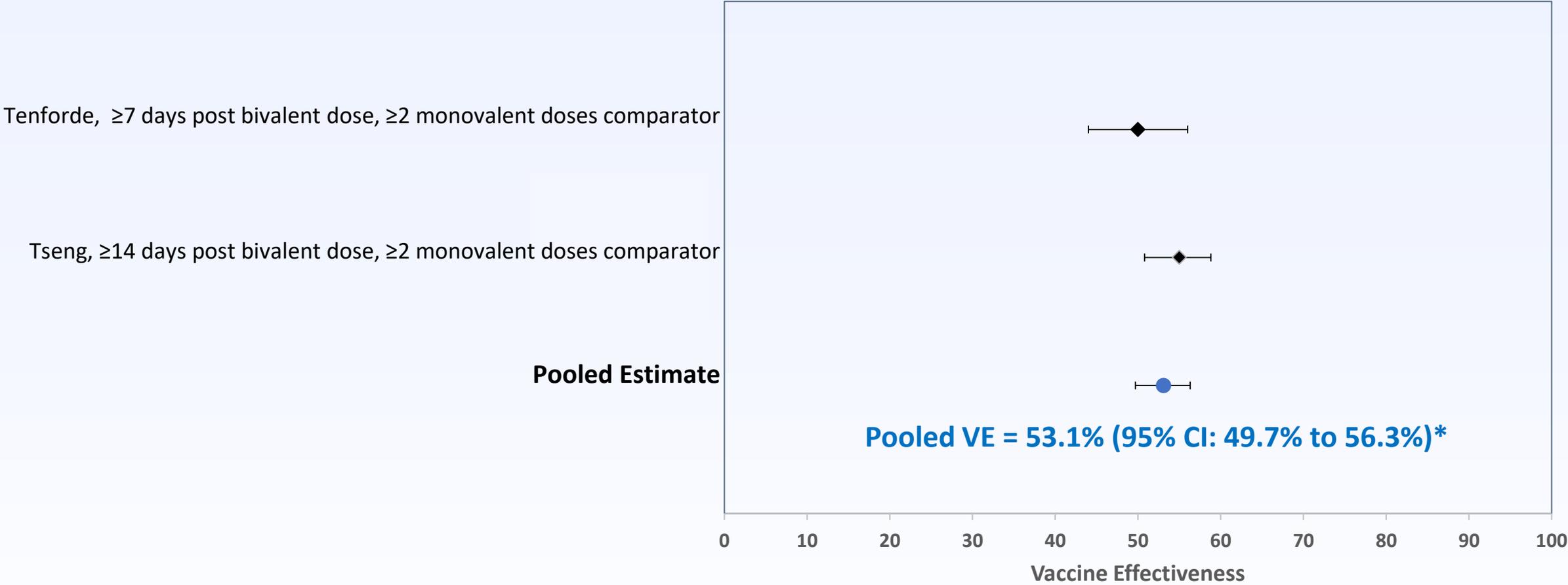


Pooling of Vaccine Effectiveness (VE) Estimates

- For each outcome, assessed body of evidence for suitability for pooling
 - Most representative study selected if multiple studies in same population
- Meta-analyses conducted
- Estimates evaluated for heterogeneity
- Resulting pooled estimates summarize real-world data available at time of GRADE analysis



Medically-Attended COVID-19 (ED/UC Visits), Adults and Adolescents (n=2)



Pooled VE = 53.1% (95% CI: 49.7% to 56.3%)*

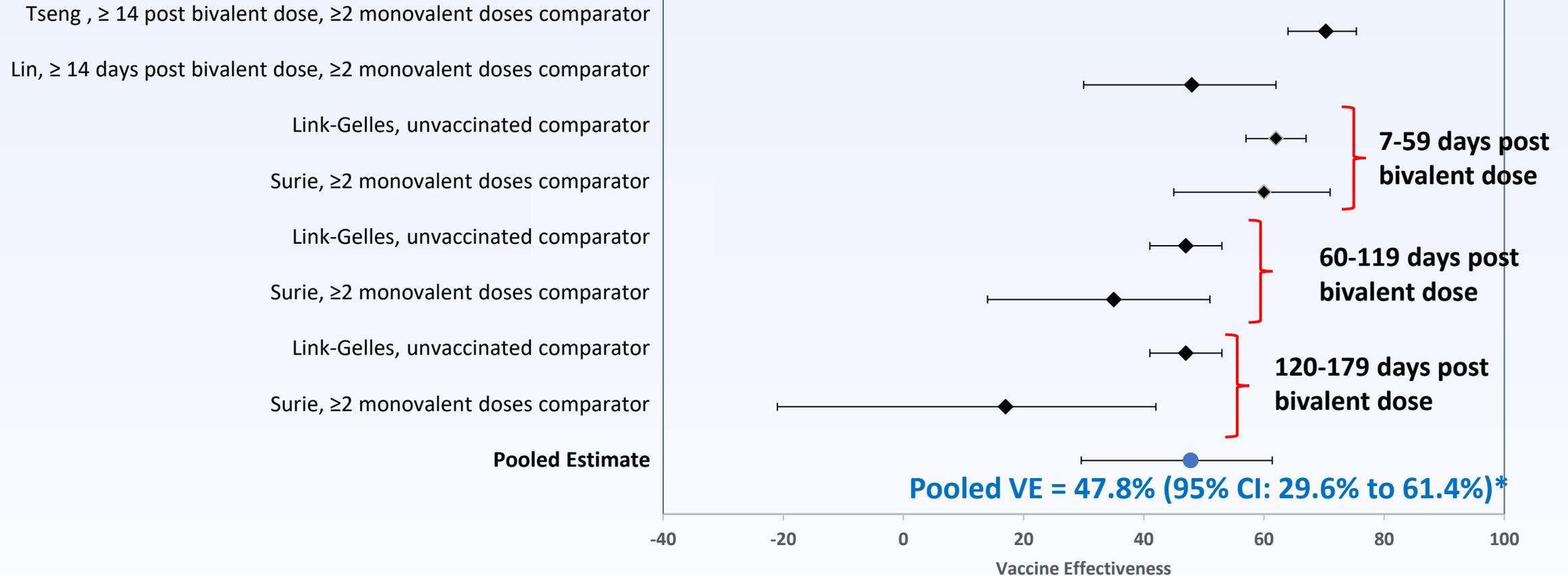
*Pooled RR based on a fixed effects meta-analysis, using adjusted vaccine effectiveness estimates on a log scale. Fixed effects model was used for this analysis due to imprecise estimates of the between-studies variance.

GRADE: Medically-Attended COVID-19 (ED/UC Visits), Adults and Adolescents (n=2)

- **Observational Studies (n=2)**
 - Pooled RR 0.47 (95% CI: 0.44 to 0.50)
 - No serious concerns in certainty assessment.
 - Evidence type: **Low certainty**



Hospitalization due to COVID-19, Adults and Adolescents (n=4)



*Pooled RR based on a random effects meta-analysis, using adjusted vaccine effectiveness estimates on a log scale.

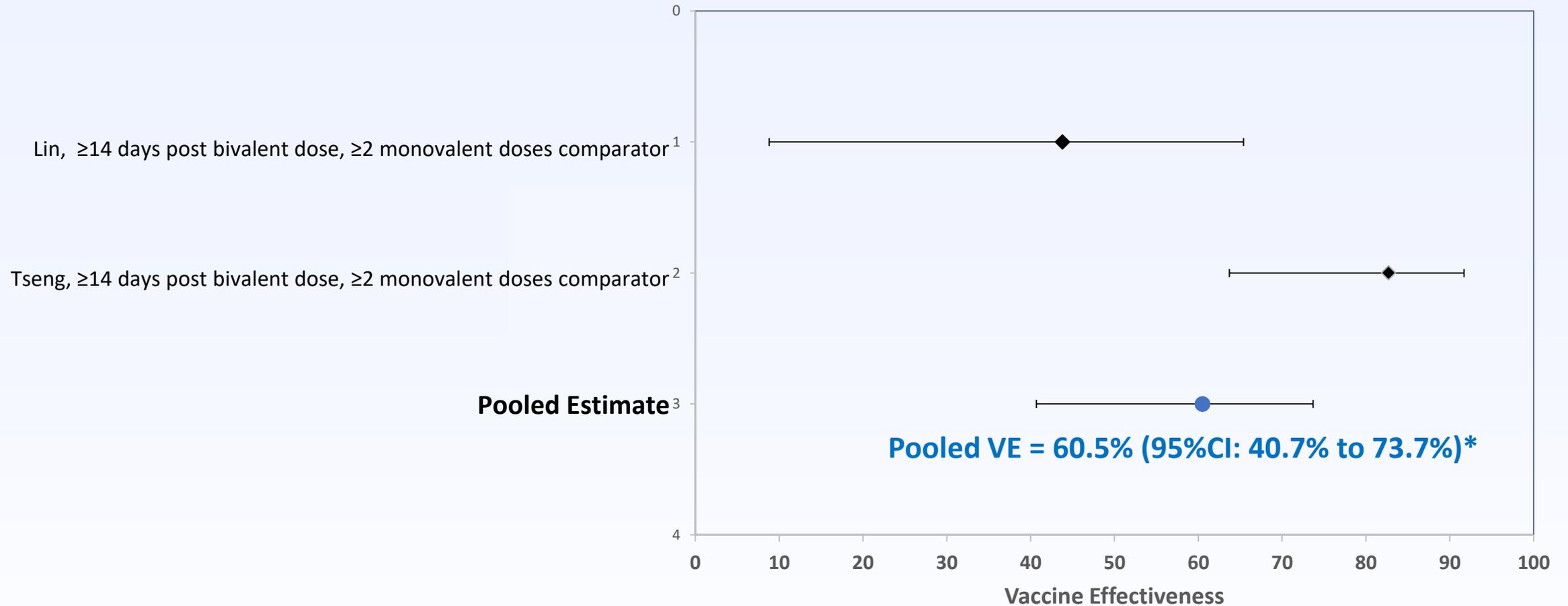
Note: 6 studies were identified in the systematic review, however 2 studies had overlapping populations and were excluded from the pooled analysis.

GRADE: Hospitalization due to COVID-19, Adults and Adolescents (n=4)

- **Observational Studies (n=4)**
 - Pooled RR 0.52 (95% CI: 0.39–0.70)
 - No serious concerns in certainty assessment.
 - Evidence type: **Low certainty**



Death due to COVID-19, Adults and Adolescents (n=2)

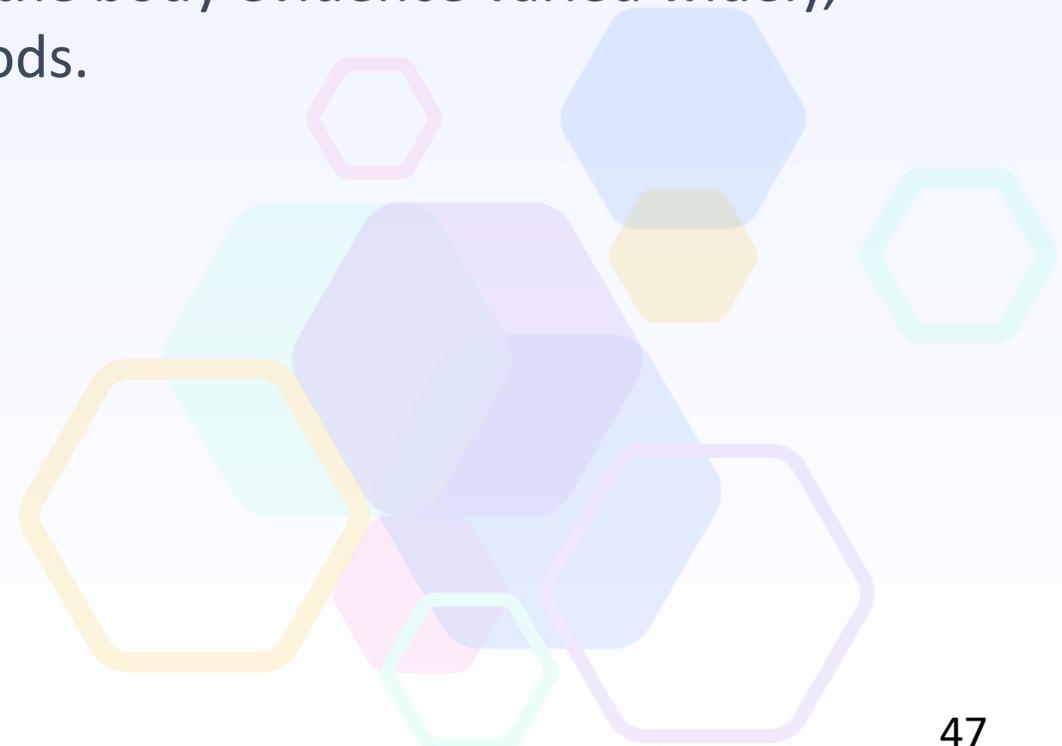


*Pooled RR based on a fixed effects meta-analysis, using adjusted vaccine effectiveness estimates on a log scale. Fixed effects model was used for this analysis due to imprecise estimates of the between-studies variance.

GRADE: Death due to COVID-19, Adults and Adolescents (n=2)

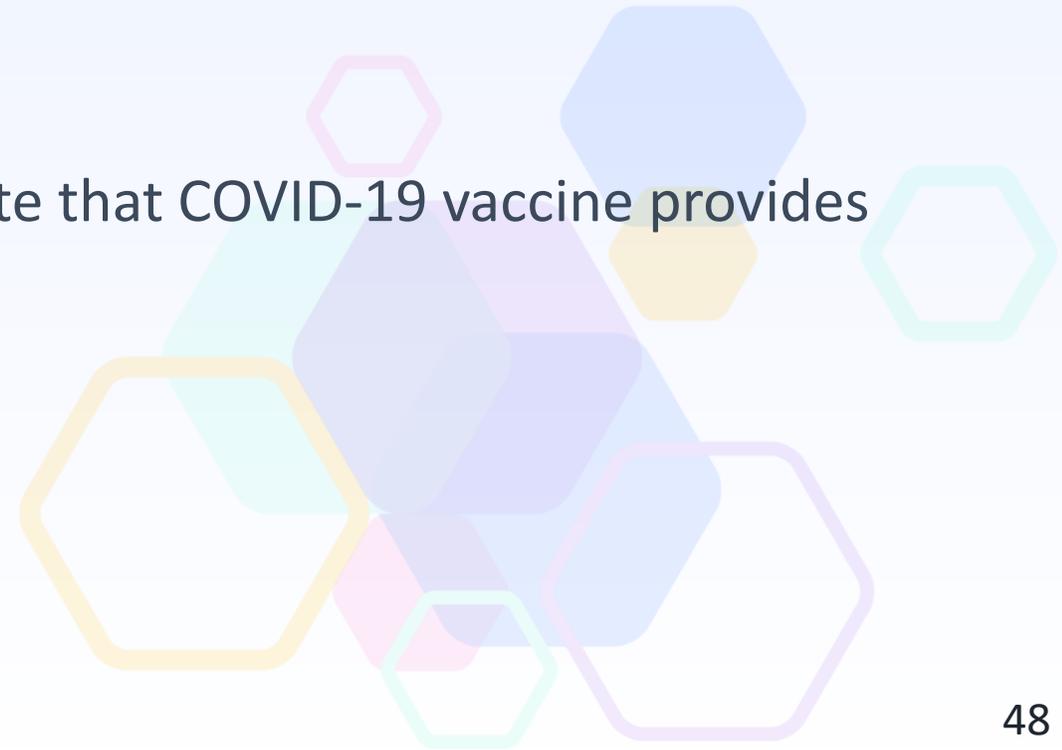
- **Observational Studies (n=2)**

- Pooled RR 0.39 (95% CI: 0.26 to 0.59)
- Serious concern for inconsistency was present. The magnitude of effect and 95% confidence intervals from the two studies in the body evidence varied widely, possibly reflecting differences in study methods.
- Evidence type: **Very low**



Post-COVID-Conditions, Adults and Adolescents

- No published or preprint captured in systematic review
- Common reasons for exclusion
 - Review article
 - Self-reported vaccination status
 - Combines vaccine platforms
 - Not a VE study
 - Vaccination as a therapeutic (after infection)
- Data not captured in the systematic review indicate that COVID-19 vaccine provides some protection against post-COVID conditions



Specified Serious Adverse Events (Myocarditis/Pericarditis)

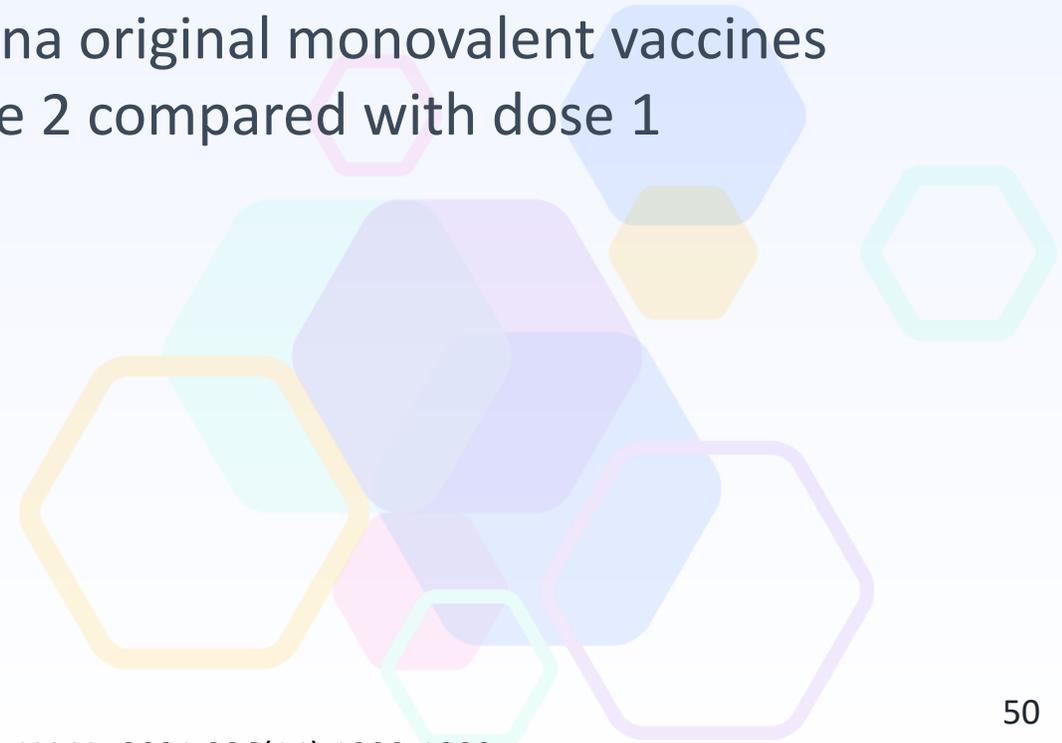
Incidence Rate of Verified Myocarditis/Pericarditis in the 0 to 7 Days After mRNA COVID-19 Vaccination among Persons Aged 12 – 39 Years by Product, Age Group, Sex.

Age group	Monovalent Booster Dose		Bivalent Booster Dose	
	Cases/Doses Administered	Incidence Rate/Million Doses (95% CI)	Cases/Doses Administered	Incidence Rate/Million Doses (95% CI)
Pfizer				
Male				
12-17 y	-	-	0/55649	0.0 (0.0 – 53.8)
12-15 y	5/81613	61.3 (19.9 – 143.0)	-	-
16-17 y	9/47874	188.0 (86.0 – 356.9)	-	-
18-29 y	7/166973	41.9 (16.9 – 86.4)	1/60338	16.6 (0.4 – 92.3)
30-39 y	3/197554	15.2 (3.1 – 44.4)	0/97171	0.0 (0.0 – 30.8)
Female				
12-17 y	-	-	0/57776	0.0 (0.0 – 51.9)
12-15 y	0/84114	0.0 (0.0 – 35.6)	-	-
16-17 y	2/55004	36.4 (4.4 – 131.3)	-	-
18-29 y	1/240226	4.2 (0.1 – 23.2)	0/95162	0.0 (0.0 – 31.5)
30-39 y	1/268412	3.7 (0.1 – 20.8)	0/133305	0.0 (0.0 – 22.5)
Moderna				
Male				
18-29 y	7/109337	64.0 (25.7 – 131.9)	0/22247	0.0 (0.0 – 134.7)
30-39 y	1/149468	6.7 (0.2 – 37.3)	1/41820	23.9 (0.6 – 133.2)
Female				
18-29 y	1/156707	6.4 (0.2 – 35.6)	0/35393	0.0 (0.0 – 84.6)
30-39 y	2/191765	10.4 (1.3 – 37.7)	0/55816	0.0 (0.0 – 53.7)

Source: Goddard K, et al. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States. Ann Intern Med. 2022;175:1169-1771. **Bivalent booster data through March 11, 2023. Data unpublished.** 49

Specified Serious Adverse Events (Anaphylaxis), Adults and Adolescents

- Among persons 12 and older, based on events occurring in a 0-1 day risk interval after vaccination, the estimated incidence of confirmed anaphylaxis among adolescents and adults was:
 - 4.8 (95% CI 3.2-6.9) per million doses of Pfizer-BioNTech original monovalent vaccines
 - 5.1 (95% CI: 3.3-7.4) per million doses of Moderna original monovalent vaccines
 - There were fewer cases of anaphylaxis post dose 2 compared with dose 1

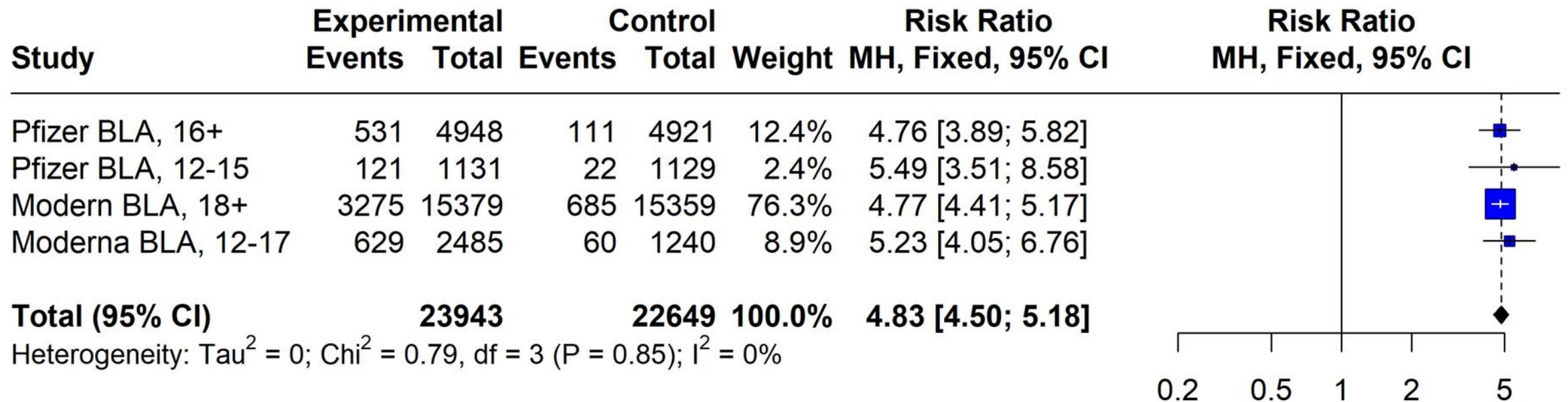


GRADE: Specified Serious Adverse Events , Adults and Adolescents

- **Observational Studies (n=2)**

- Two specific, rare SAEs have been associated with vaccination through safety surveillance
- No serious concerns in certainty assessment.
- Evidence type: **Low certainty**

Reactogenicity*, Severe (Grade ≥ 3), Adults and Adolescents (n=4)



*Reactogenicity data are from the original monovalent Moderna and Pfizer randomized controlled trials

GRADE: Reactogenicity, Severe (Grade ≥ 3), Adults and Adolescents

- **Randomized Controlled Trials (n=4)**
 - Pooled RR 4.83 (95% CI: 4.50–5.18)
 - Very serious concern for indirectness, as the body of evidence did not include anyone who received an updated dose, were from a prior period of the pandemic, and excluded persons with prior COVID-19 infection, pregnant or breastfeeding women, and persons who were immunocompromised.
 - Evidence type: **Low certainty**

Summary of GRADE – Adults and Adolescents

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
Medically-attended COVID-19 (ED/UC visit)	Critical	OBS (2)	Updated COVID-19 vaccine is effective in preventing medically attended COVID-19 ED/UC visits.	Low
Hospitalization due to COVID-19	Critical	OBS (4)	Updated COVID-19 vaccine prevents hospitalization due to COVID-19	Low
Death due to COVID-19	Important	OBS (2)	Updated COVID-19 vaccine prevents death due to COVID-19	Very low
Post-COVID Conditions	Important	OBS (0)	-	-
Harms				
Serious adverse events	Critical	OBS (2)	In post-authorization safety monitoring, myocarditis and anaphylaxis were rare but more common following vaccination	Low
Reactogenicity	Important	RCT (4)	Severe reactions within 7 days were more common in vaccinated	Low

Infants and Children Benefits GRADE:

Adolescent and adult benefits downgraded for indirectness

- Systematic review for benefits of vaccination did not capture a sufficient amount of data for evidence synthesis in pediatrics, however data in adults provide indirect evidence of benefits

			Adolescents and Adults	Pediatrics (with indirectness downgrade)
Outcome	Design (# of studies)	Pooled VE (95% CI)	Evidence type	Evidence type
Medically-attended COVID-19 (ED/UC visit)	OBS (2)	53.1 (49.7-56.3)	Low	Very low
Hospitalization due to COVID-19	OBS (4)	47.8 (29.6-61.4)	Low	Very low
Death due to COVID-19	OBS (2)	60.5 (40.7-73.7)	Very low	Very low

Specified Serious Adverse Events (Myocarditis/Pericarditis), Infants and Children

- A single observational study from the Vaccine Safety Datalink (VSD) evaluated chart-reviewed cases of myocarditis occurring among children aged 5-11 years following a monovalent booster based on events occurring in a 7-day risk interval after vaccination vs. a comparison interval in vaccinated individuals.

Table. Incidence Rate of Verified Myocarditis/Pericarditis in the 0 to 7 Days After mRNA COVID-19 Vaccination among Persons Aged 5-11 Years by Age Group and Sex.

Age group	Cases/Monovalent Booster Doses Administered	Incidence Rate/Million Doses (95% CI)
Pfizer		
Male		
5-11 y	0/50415	0.0 (0.0-59.4)
Female		
5-11 y	0/49261	0.0 (0.0-60.8)

Source: Goddard et al. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States. *Annals of Internal Medicine*. <https://www.acpjournals.org/doi/10.7326/M22-2274>

Specified Serious Adverse Events (Anaphylaxis), Infants and Children

- Risk of anaphylaxis in children can be indirectly inferred from the known risk in persons ages 12 and older
 - 4.8 (95% CI 3.2-6.9) per million doses of Pfizer-BioNTech original monovalent
 - 5.1 (95% CI: 3.3-7.4) per million doses of original Moderna monovalent
 - There were fewer cases of anaphylaxis post dose 2 compared with dose 1

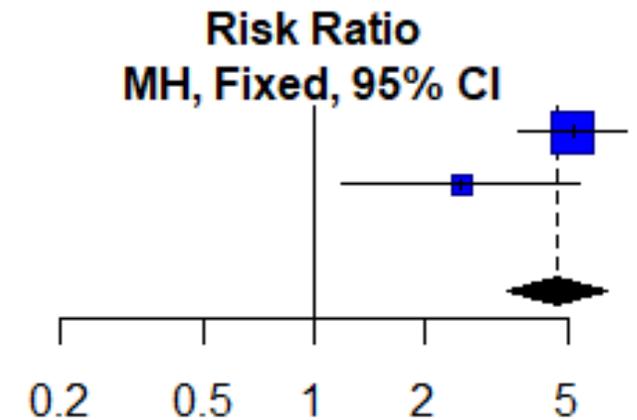
GRADE: Specified Serious Adverse Events, Infants and Children

- **Observational Studies (n=2)**
 - Two specific, rare SAEs have been associated with vaccination through safety surveillance
 - Serious concern for indirectness, as the body of evidence for myocarditis was only among children aged 5-11 receiving a monovalent booster and the body of evidence for anaphylaxis was among adults and adolescents aged 12 years and older receiving a primary series
 - Evidence type: **Very low certainty**

Reactogenicity*, Severe (Grade ≥ 3) (n=2), Infants and Children

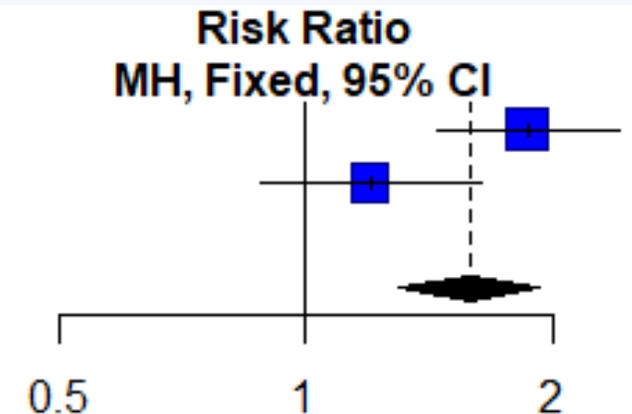
Study	Experimental		Control		Weight	Risk Ratio MH, Fixed, 95% CI
	Events	Total	Events	Total		
Moderna, 6-11 years	514	3006	33	994	82.2%	5.15 [3.65; 7.27]
Pfizer, 5-11 years	41	1517	8	750	17.8%	2.53 [1.19; 5.38]
Total (95% CI)	4523		1744		100.0%	4.69 [3.43; 6.41]

Heterogeneity: $\text{Tau}^2 = 0.1625$; $\text{Chi}^2 = 2.82$, $\text{df} = 1$ ($P = 0.09$); $I^2 = 65\%$



Study	Experimental		Control		Weight	Risk Ratio MH, Fixed, 95% CI
	Events	Total	Events	Total		
Moderna, 6mo-5 years	366	4774	65	1582	57.6%	1.87 [1.44; 2.41]
Pfizer, 6mo-4 years	129	3010	54	1510	42.4%	1.20 [0.88; 1.64]
Total (95% CI)	7784		3092		100.0%	1.58 [1.30; 1.93]

Heterogeneity: $\text{Tau}^2 = 0.0767$; $\text{Chi}^2 = 4.61$, $\text{df} = 1$ ($P = 0.03$); $I^2 = 78\%$



*Reactogenicity data are from the original monovalent Moderna and Pfizer randomized controlled trials.

GRADE: Reactogenicity, Severe (Grade ≥ 3) (n=2)

- RCTs (n=2)
 - Pooled RR 4.69 (95% CI: 3.43–6.41)
 - Very serious concern for indirectness was present. The available body of evidence did not include anyone who received an updated dose and excluded children were immunocompromised. While children with a history of COVID-19 infection were included in the safety sets, the RCTs were conducted at a time of low seroprevalence.
 - Evidence type: **Low certainty**

Summary of GRADE – Infants and Children

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
Medically-attended COVID-19 (ED/UC visit)	Critical	OBS (2)	Updated COVID-19 vaccine is effective in preventing medically attended COVID-19 ED/UC visits, although the body of evidence is limited to indirect data from adolescents and adults	Very low
Hospitalization due to COVID-19	Critical	OBS (4)	Updated COVID-19 vaccine prevents hospitalization due to COVID-19, although the body of evidence is limited to indirect data from adolescents and adults	Very low
Death due to COVID-19	Important	OBS (2)	Updated COVID-19 vaccine prevents death due to COVID-19, although the body of evidence is limited to indirect data from adolescents and adults	Very low
Post-COVID Conditions	Important	OBS (0)	-	-
MIS-C	Important	OBS (0)	-	-
Harms				
Serious adverse events	Critical	OBS (2)	In post-authorization safety monitoring, two specific adverse events have been associated with vaccination	Very Low
Reactogenicity	Important	RCT (2)	Severe reactions within 7 days were more common in vaccinated	Low

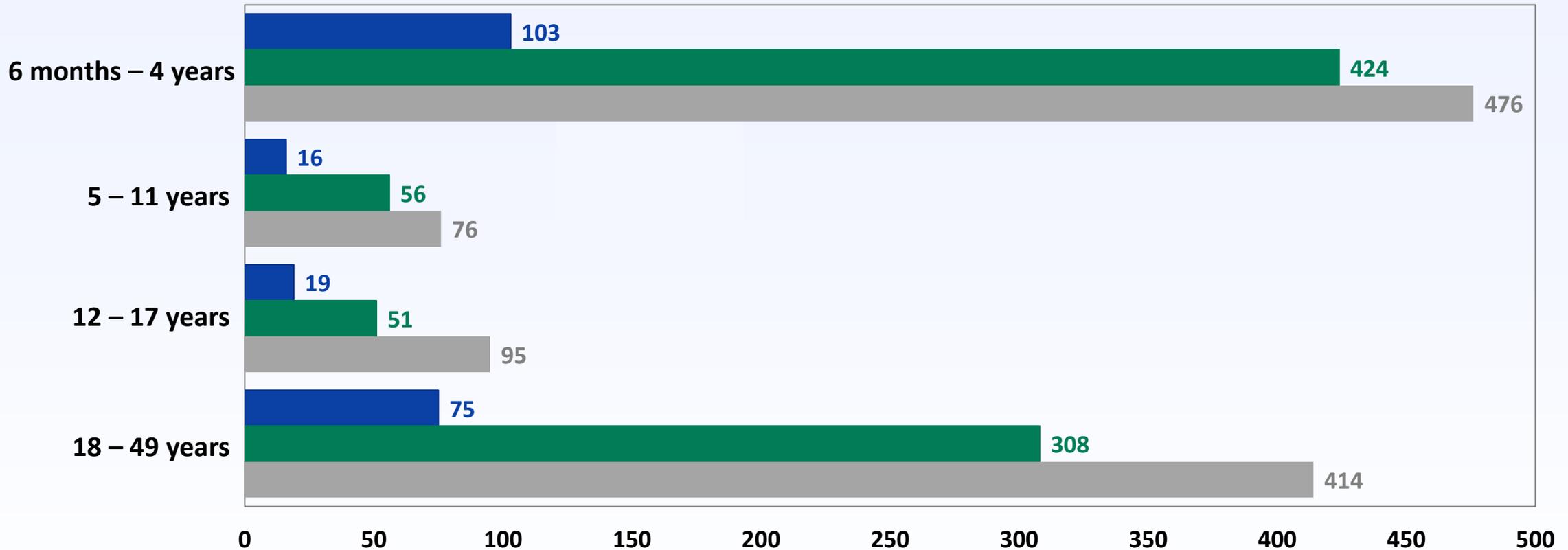
Novavax vaccine effectiveness and safety

- Due to lower uptake of Novavax COVID-19 vaccine, no post-authorization vaccine effectiveness estimates from prior COVID-19 vaccine formulation are available
- Post-authorization safety data are also limited by the low number of doses administered¹
 - Available data from the Vaccine Adverse Event Reporting System (VAERS) are consistent with those from preauthorization clinical trials
 - Most VAERS reports were classified as nonserious
 - The most commonly reported AEs included dizziness, fatigue, and headache
 - No new safety concerns were identified

1. <https://www.cdc.gov/mmwr/volumes/72/wr/mm7231a4.htm>

Estimated COVID-19 hospitalizations prevented over 6 months for every million mRNA COVID-19 doses, among those age <50 years, by age group

Based on hospitalization rates from **Spring 2023 (low)**, **December 2022 (high winter)**, Summer 2022 (high past year)



Calculating Risk: Myocarditis and COVID-19 vaccines

- Limited data to inform myocarditis risk after bivalent COVID-19 vaccine booster dose
 - Myocarditis rates following **booster doses** in adolescent and young adult males are **lower** than rates following **primary series**, but estimates are limited by fewer numbers of doses for both the bivalent boosters and the previous monovalent boosters administered in VSD¹
- Myocarditis risk **lower** with **longer time between doses**
 - Rates of myocarditis **lower** with **extended interval** between dose 1 and dose 2 for primary series²
 - Longer interval between updated doses may also impact myocarditis rates
- Most individuals with myocarditis/pericarditis have **fully recovered** at follow-up³
- The risk of adverse cardiac outcomes were **1.8 – 5.6 times higher** after SARS-CoV-2 infection than after mRNA COVID-19 vaccination among males ages 12-17 years⁴

¹ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-24/COVID-02-Shimabukuro-508.pdf>

² <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/11-COVID-Moulia-508.pdf>

³ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf>

⁴ https://www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm?s_cid=mm7114e1_w

Estimated COVID-19 hospitalizations prevented vs. potential myocarditis cases for every million mRNA COVID-19 vaccine doses: 12 – 17-year-olds¹

Per million doses in 12 – 17-year-olds over 6 months²



19 – 95 hospitalizations prevented



5 – 19 ICU admissions prevented

0 – 1 death prevented



0 myocarditis³ cases in 55,649 males with a bivalent dose

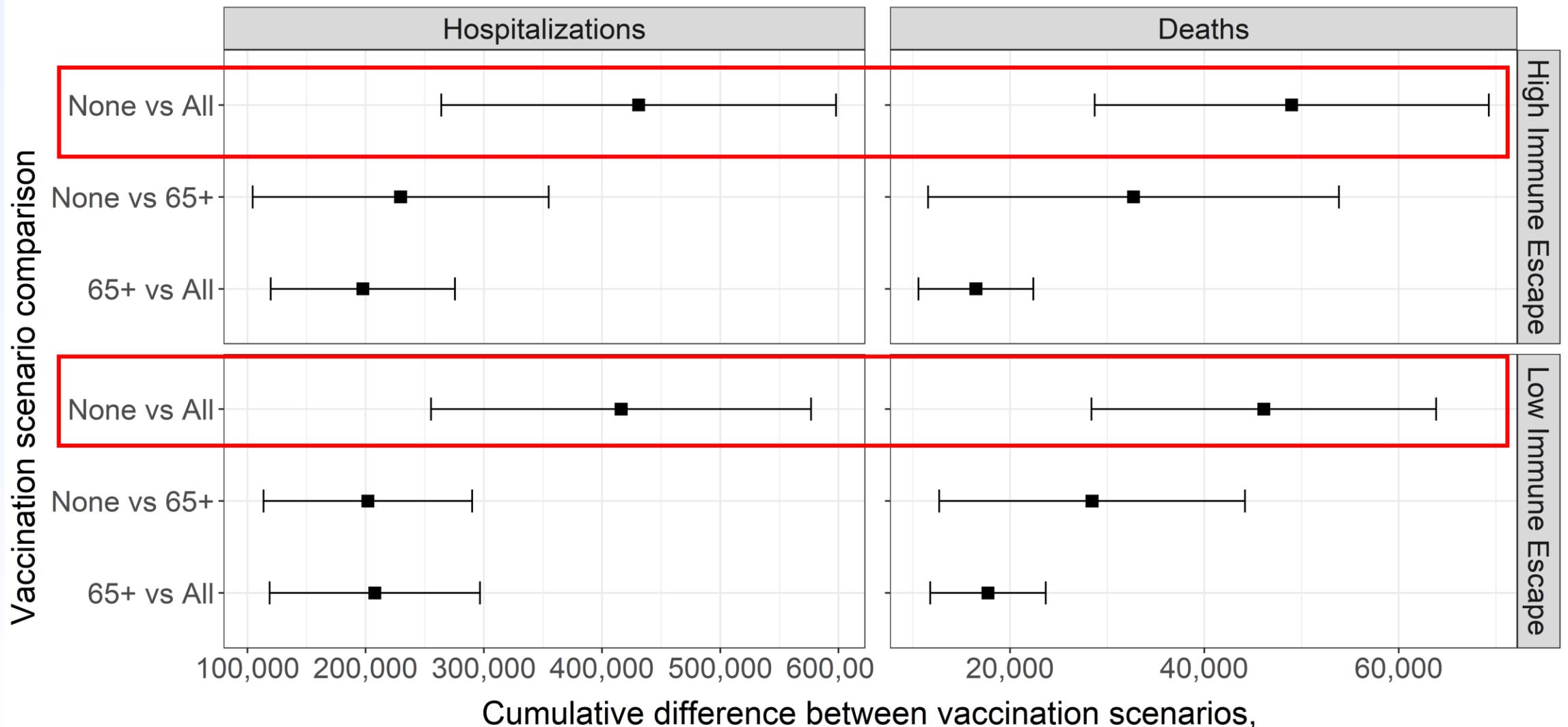
0 myocarditis³ cases in 57,776 females with a bivalent dose

¹ Results were adjusted to account for potential incidental findings of SARS-CoV-2 infection by multiplying the estimated hospitalizations, ICU admissions, and deaths prevented by the estimated percent of COVID-NET hospitalizations that are likely due to COVID-19 among 12 – 17-year-olds during on Omicron BA.5 predominant period (55%)

² Ranges presented for benefits are based on the high and low incidence scenarios presented on slides 7 and 8

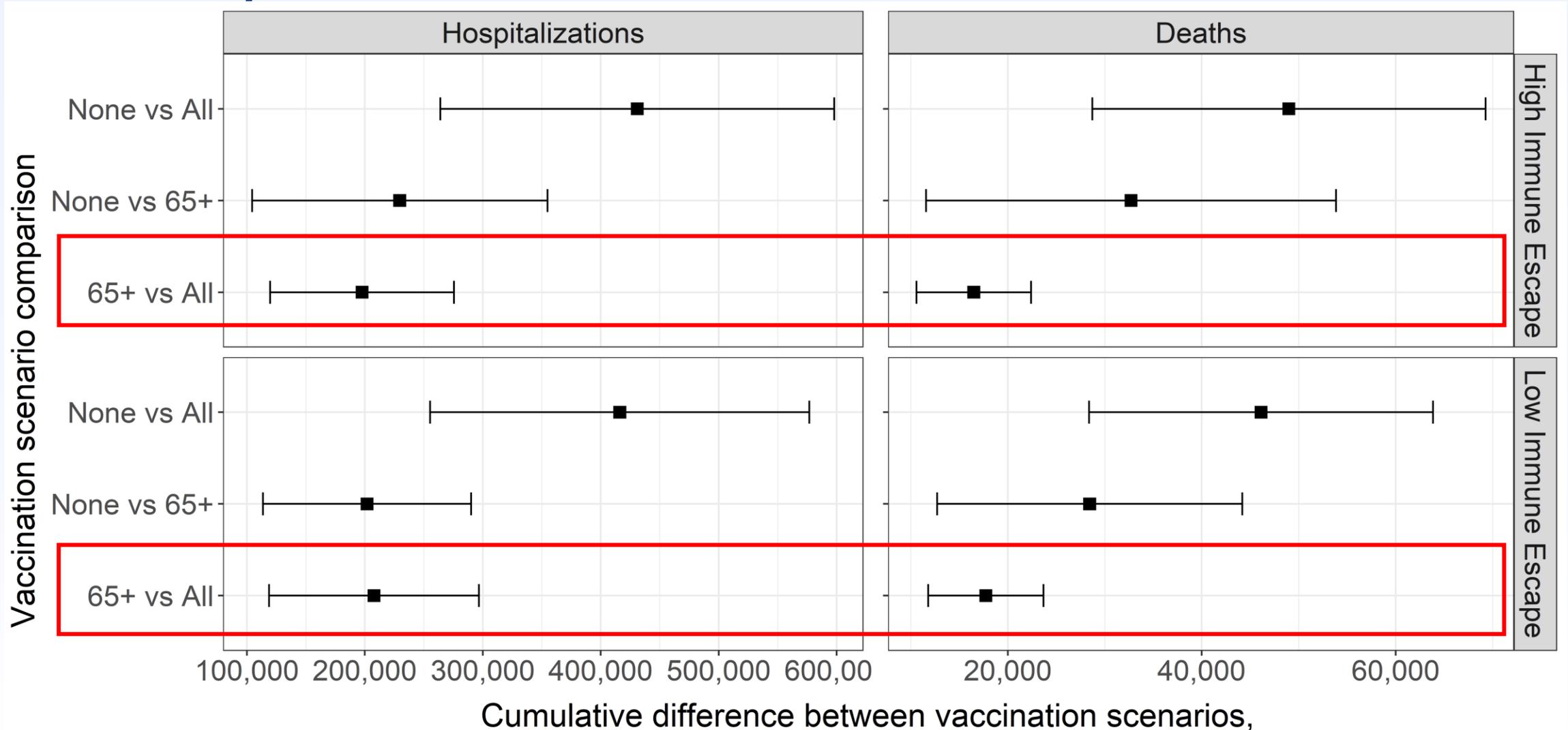
³ Based on preliminary Pfizer-BioNTech bivalent booster safety data from VSD (incident rate/million doses): 0 (95% CI: 0-54) in males and 0 (95% CI: 0-52) in females

Universal vaccine recommendations projected to prevent about 400,000 hospitalizations and 40,000 deaths over the next 2 years compared with no recommendation, regardless of level of immune escape



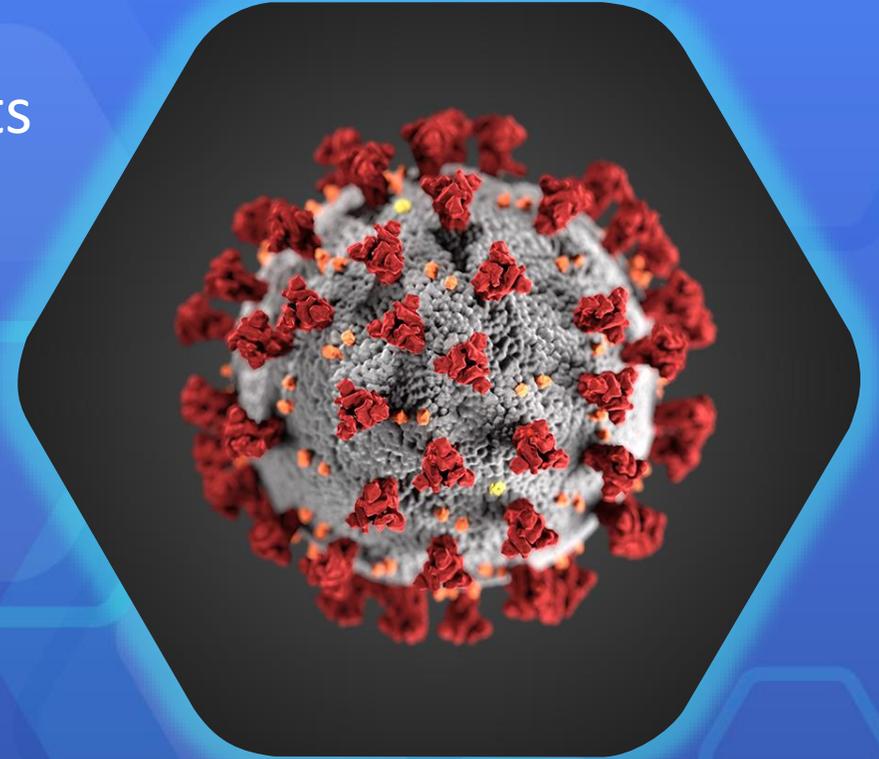
Cumulative difference between vaccination scenarios,
April 16, 2023 to April 19, 2025

Compared with only vaccinating those 65+ years, universal vaccine recommendations projected to prevent about 200,000 more hospitalizations and 15,000 more deaths over the next 2 years



Domain Equity Question:

Are the desirable and undesirable anticipated effects demonstrated across all populations equally?



Are the desirable and undesirable anticipated effects demonstrated across all populations equally?

- There is no evidence to suggest that COVID-19 vaccine effectiveness varies substantially by race/ethnicity^{1,2}
 - Differences in vaccine hesitancy/uptake, crowding, access to care, and prior infection could impact vaccine effectiveness and these factors may also differ by race/ethnicity
- There is no evidence to suggest that COVID-19 vaccine safety profiles vary by race/ethnicity, however risk has been shown to differ by age and sex
 - Risk for myocarditis is highest in adolescent and young adult males
- Benefits and harms for the U.S. population are best assessed when clinical trial and study populations are optimally representative of the U.S. population

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9619452/>

2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9763212/>

Summary

Benefits and Harms

- Monovalent XBB containing COVID-19 vaccines **increase the immune response** against the currently circulating variants
- Last year's updated vaccine was **effective** at preventing medically attended COVID-19, hospitalization due to COVID-19, and death due to COVID-19
- Accumulating evidence that COVID-19 vaccination reduces Post-COVID Conditions among both children and adults
- COVID-19 vaccines have a **high degree** of safety
 - Rare events of myocarditis and anaphylaxis have been seen in post-authorization studies
 - Unlikely that updating the formulation would increase adverse event rates
- **Benefits** are anticipated in all age groups; benefits of COVID-19 vaccines vary by **age** and incidence of COVID-19 hospitalizations
- **Benefits outweigh risks** in age groups for which risk of myocarditis is highest
- Modeling projects **more hospitalizations and deaths averted** when updated doses are **universally recommended** compared to no recommendation or recommended only for persons ≥ 65 years

Benefits and Harms

How substantial are the desirable anticipated effects?

- How substantial are the anticipated effects for each main outcome for which there is a desirable effect?

Minimal Small Moderate Large Varies Don't know

Majority opinion

Minority opinion

Benefits and Harms

How substantial are the undesirable anticipated effects?

- How substantial are the anticipated effects for each main outcome for which there is an undesirable effect?

Minimal

Small

Moderate

Large

Varies

Don't know

Benefits and Harms

Do the desirable effects outweigh the undesirable effects?

- What is the balance between the desirable effects relative to the undesirable effects?

Favors intervention (2023 – 2024 COVID-19 vaccine)

Favors comparison (no vaccine)

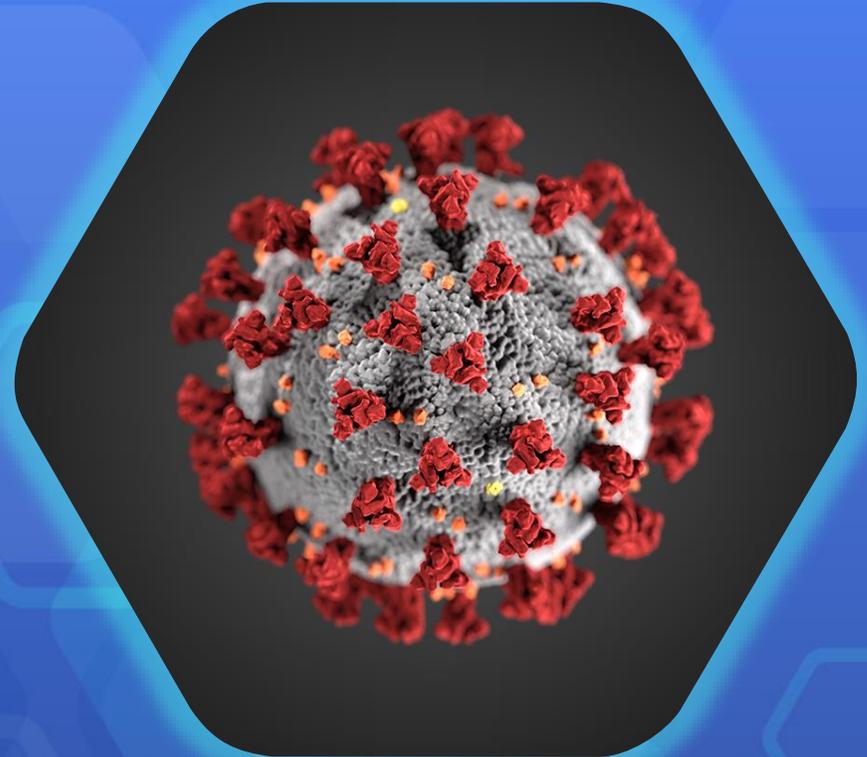
Favors both

Favors neither

Unclear

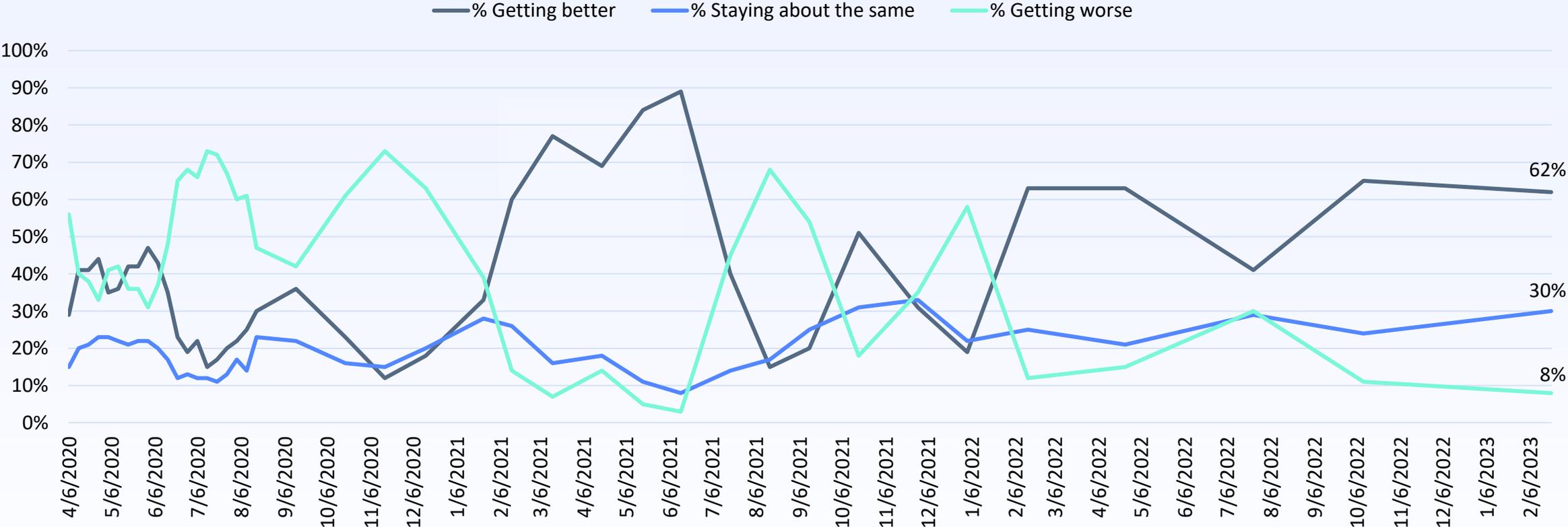
EtR Domain:

Values



Americans' assessment of COVID-19 in the U.S., February 2023

What's your impression of the coronavirus situation in the U.S. today?

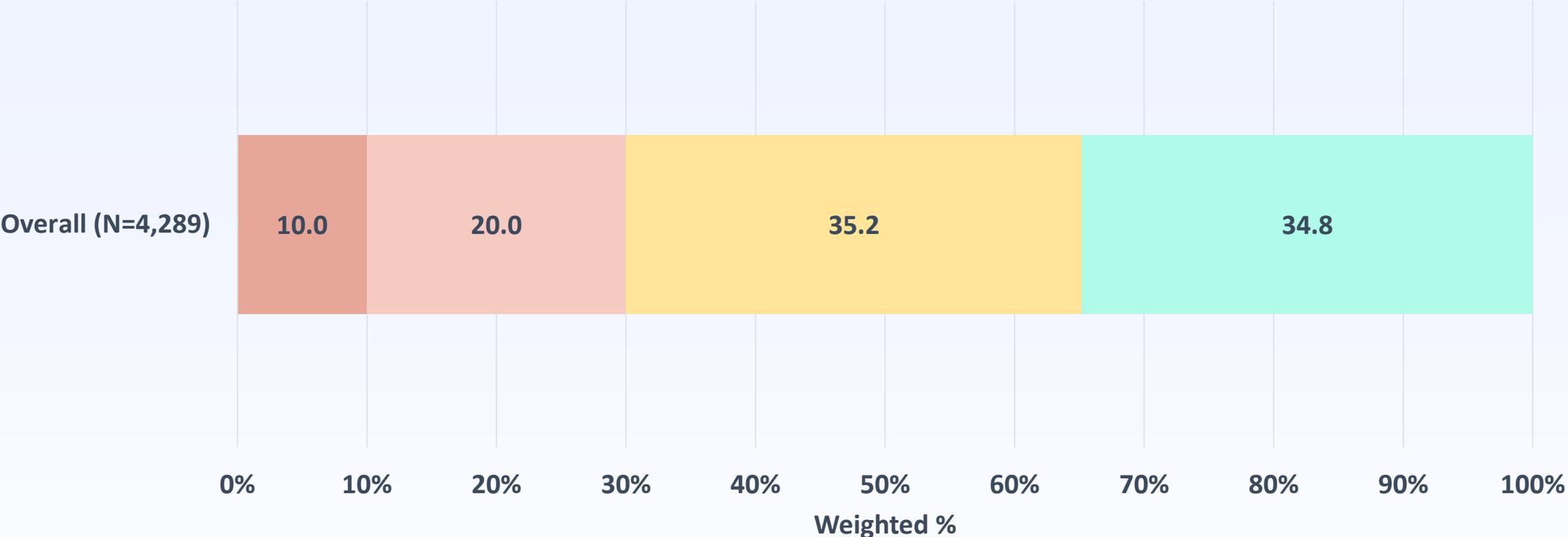


A nationally representative survey of U.S. adults conducted February 21-28 by web using the Gallup Panel

GALLUP. At Year Three, Americans Split on Whether Pandemic Is Over. <https://news.gallup.com/poll/471734/year-three-americans-split-whether-pandemic.aspx> Accessed August 29, 2023

30% of U.S. adults report they are very or moderately concerned about getting COVID-19, August 2023

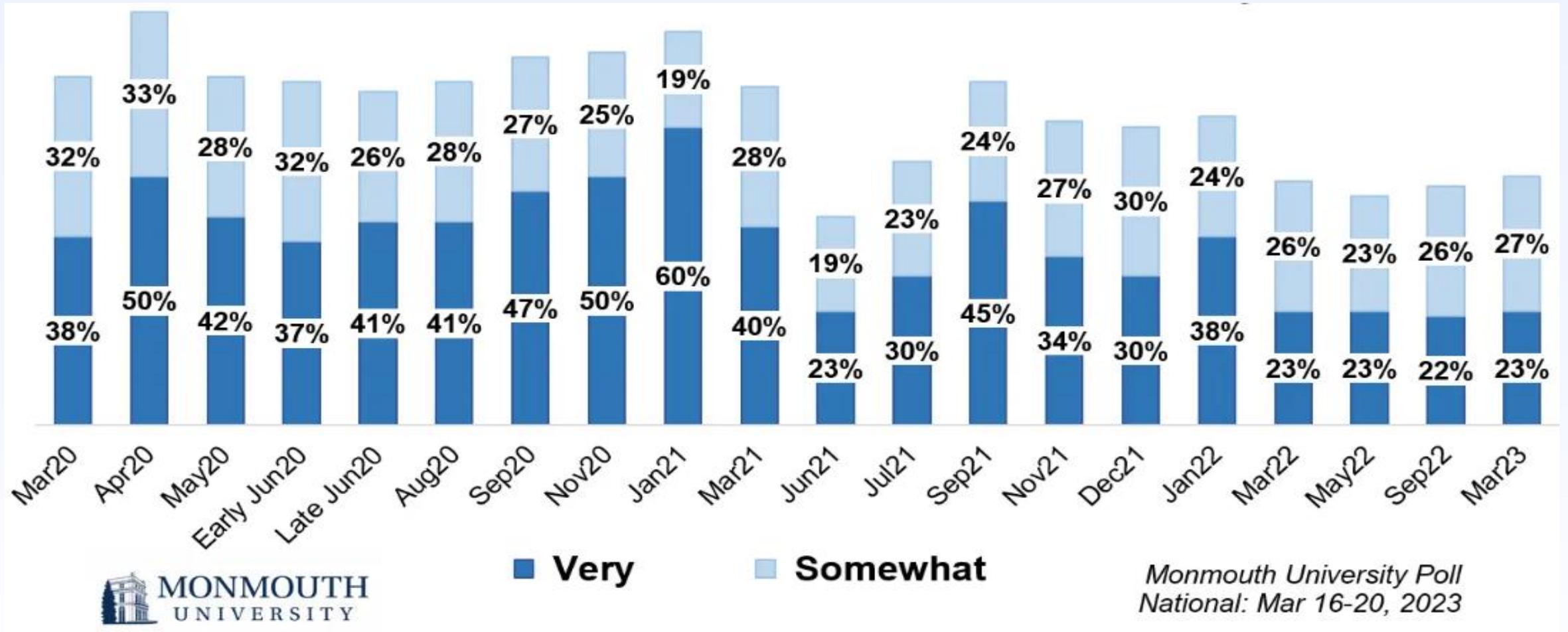
Very concerned Moderately A little Not at all



A nationally representative sample of U.S. adults aged 18 years and older

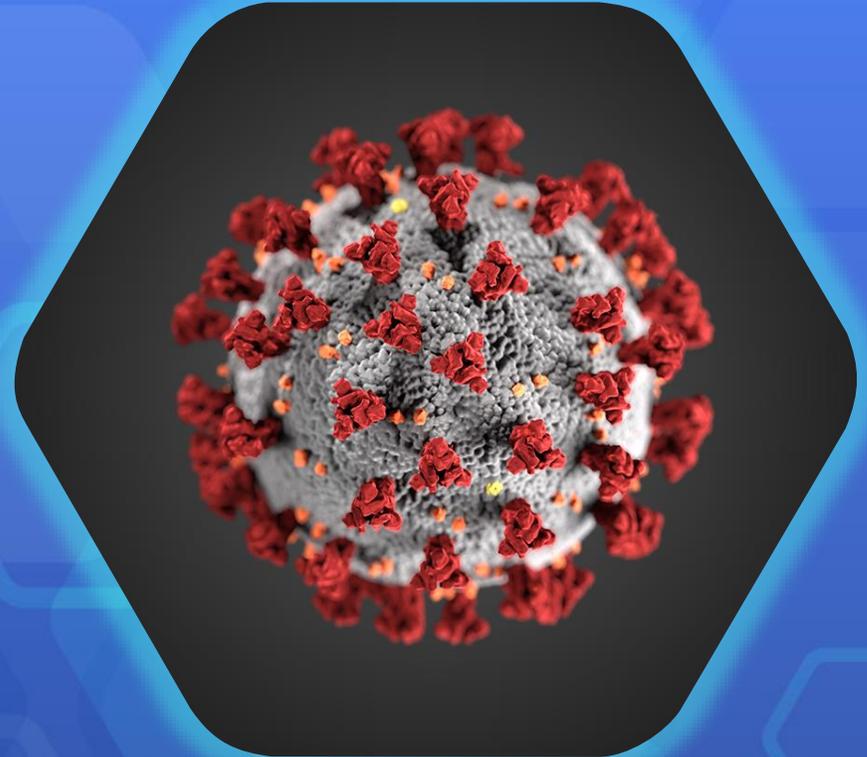
IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Concern about serious COVID-19 illness in family, March 2023

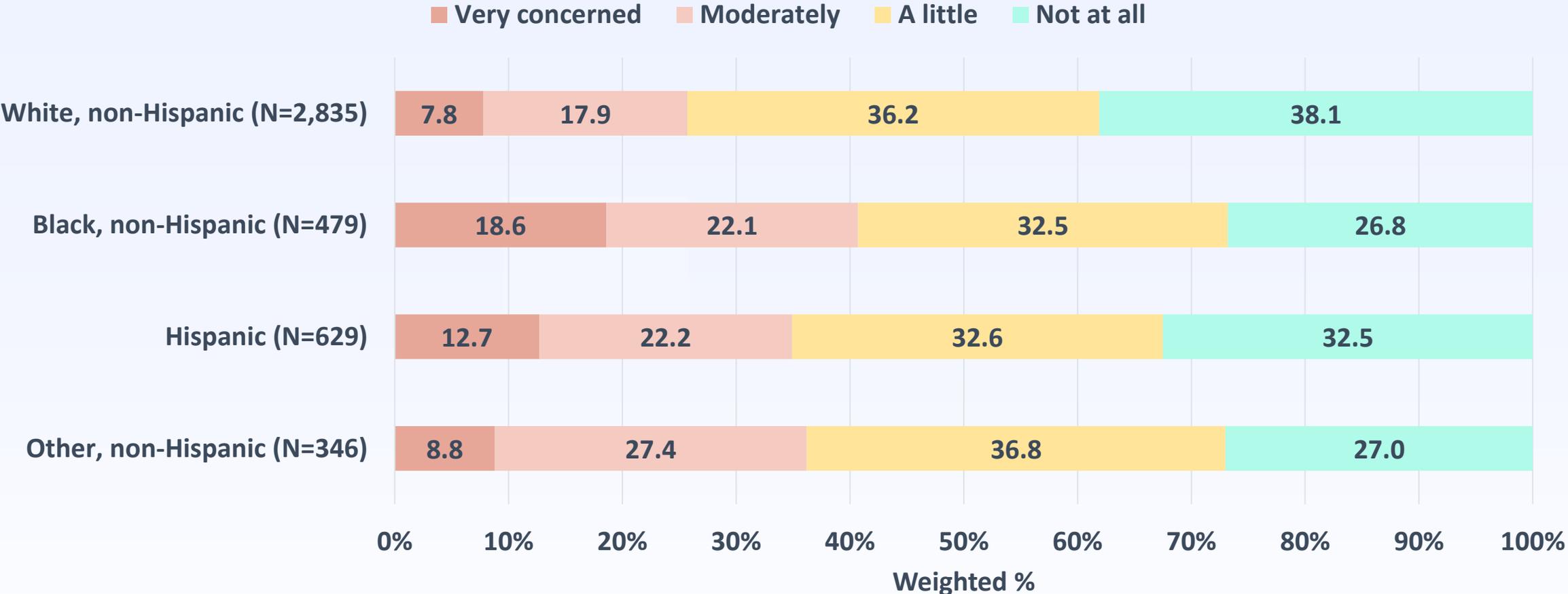


Domain Equity Question:

Is there important variability in how patients or populations value the outcome?



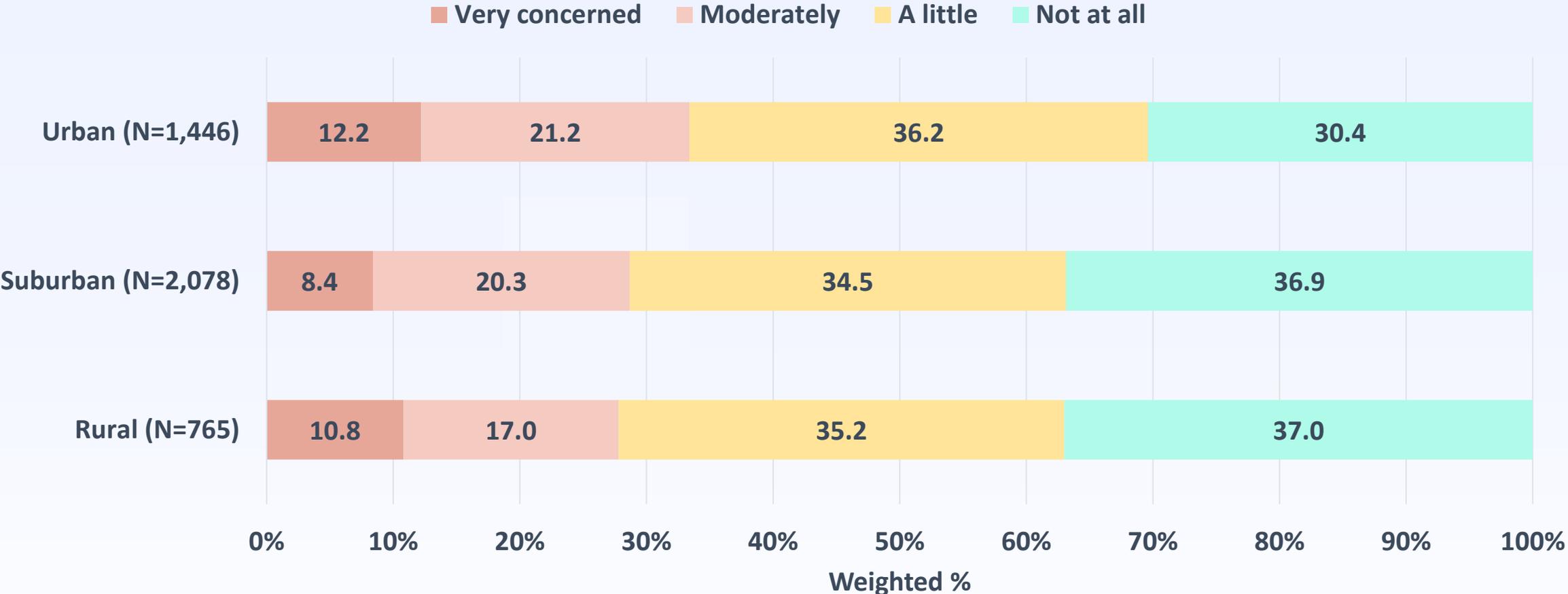
Concern about getting COVID-19 by race and ethnicity, August 2023



A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Concern about getting COVID-19 by urbanicity, U.S., August 2023

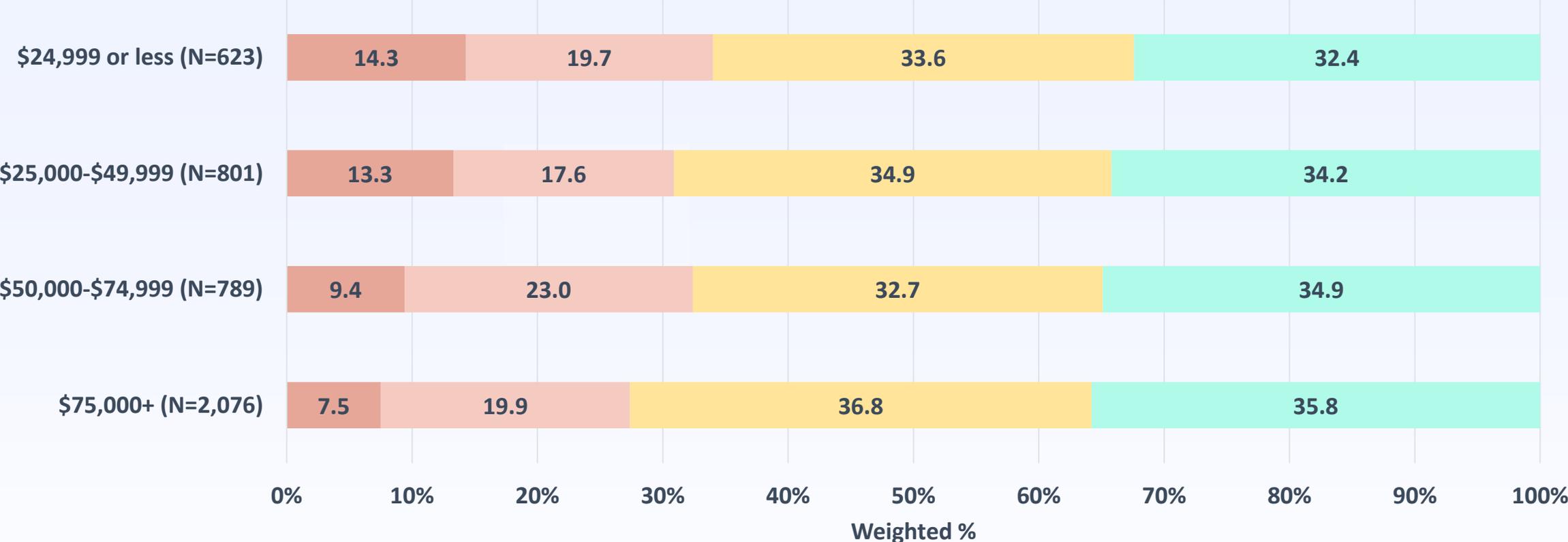


A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Concern about getting COVID-19 by income, August 2023

Very concerned Moderately A little Not at all



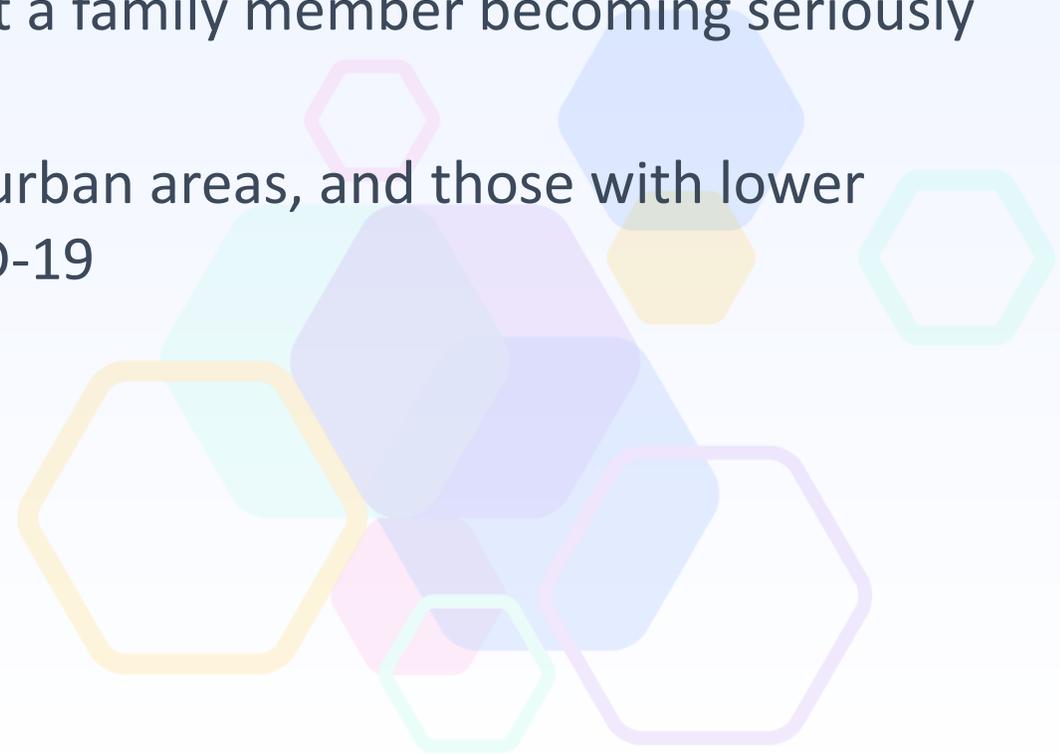
A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Summary

Values

- As of February 2023, the majority of Americans felt COVID-19 was getting better
- 30% of U.S. adults report they are very or moderately concerned about getting COVID-19
- Half of U.S. adults continue to have concern about a family member becoming seriously ill from COVID-19
- Racial and ethnic minority groups, those living in urban areas, and those with lower incomes are more concerned about getting COVID-19



Values

Criteria 1:

Does the target population feel that that the desirable effects are large relative to undesirable effects?

- How does the target population view the balance of desirable versus undesirable effects?
- Would patients/caregivers feel that the benefits outweigh the harms and burden?
- Does the population appreciate and value the 2023 – 2024 COVID-19 vaccine?

Minimal

Small

Moderate

Large

Varies

Don't know

Majority opinion

Minority opinion

Values

Criteria 2:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

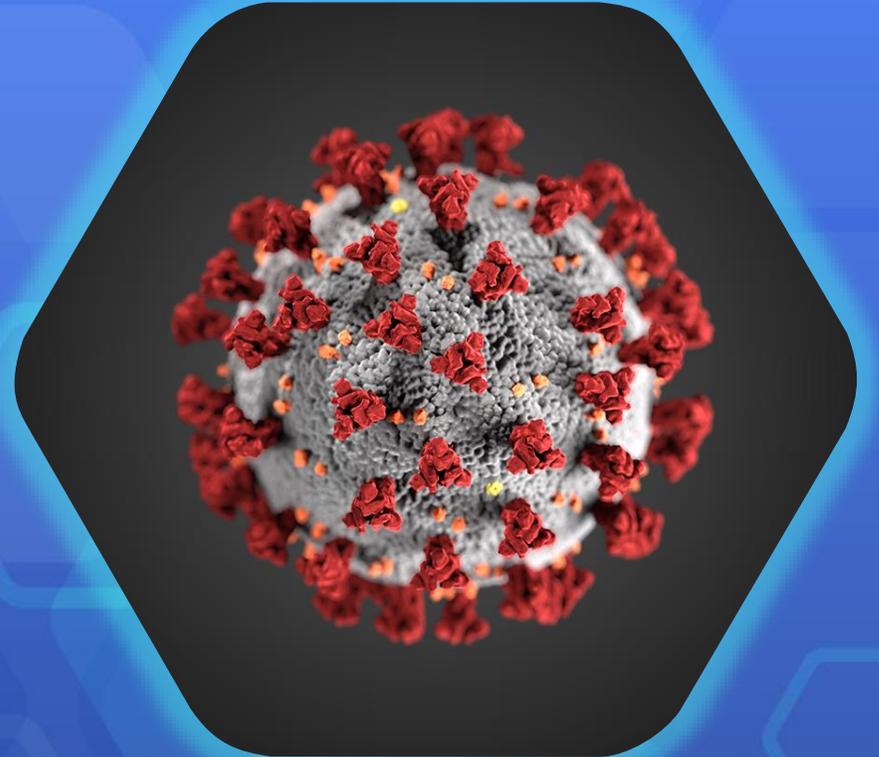
- How much do individuals value each outcome in relation to the other outcomes?
- Is there evidence to support those value judgements?
- Is there evidence that the variability is large enough to lead to different decisions?

- Important uncertainty or variability
- Probably important uncertainty or variability
- Probably not important uncertainty or variability
- No important uncertainty or variability
- No known undesirable outcomes

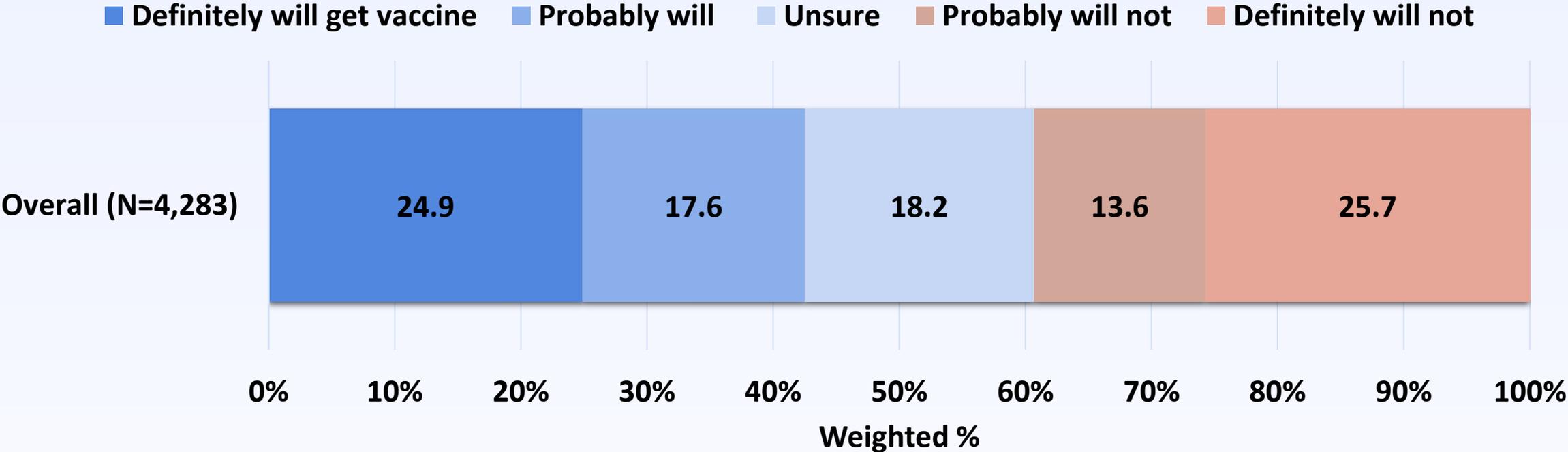
Majority opinion

Minority opinion

EtR Domain: Acceptability



Intent to get new, updated COVID-19 vaccine, August 2023

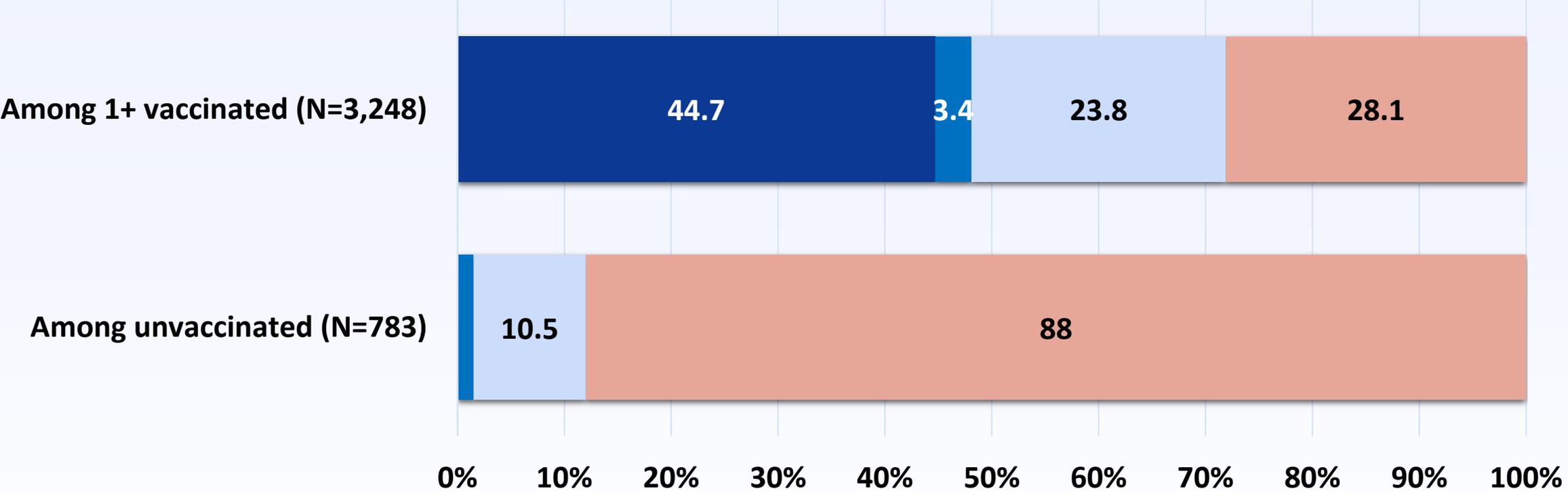


A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Bivalent COVID-19 vaccine receipt and intent among adults 18 years and older, June 2023

- Received bivalent COVID-19 vaccine
- Definitely will get vaccine
- Probabaly will get vaccine or unsure
- Probably/definitely will not get vaccine



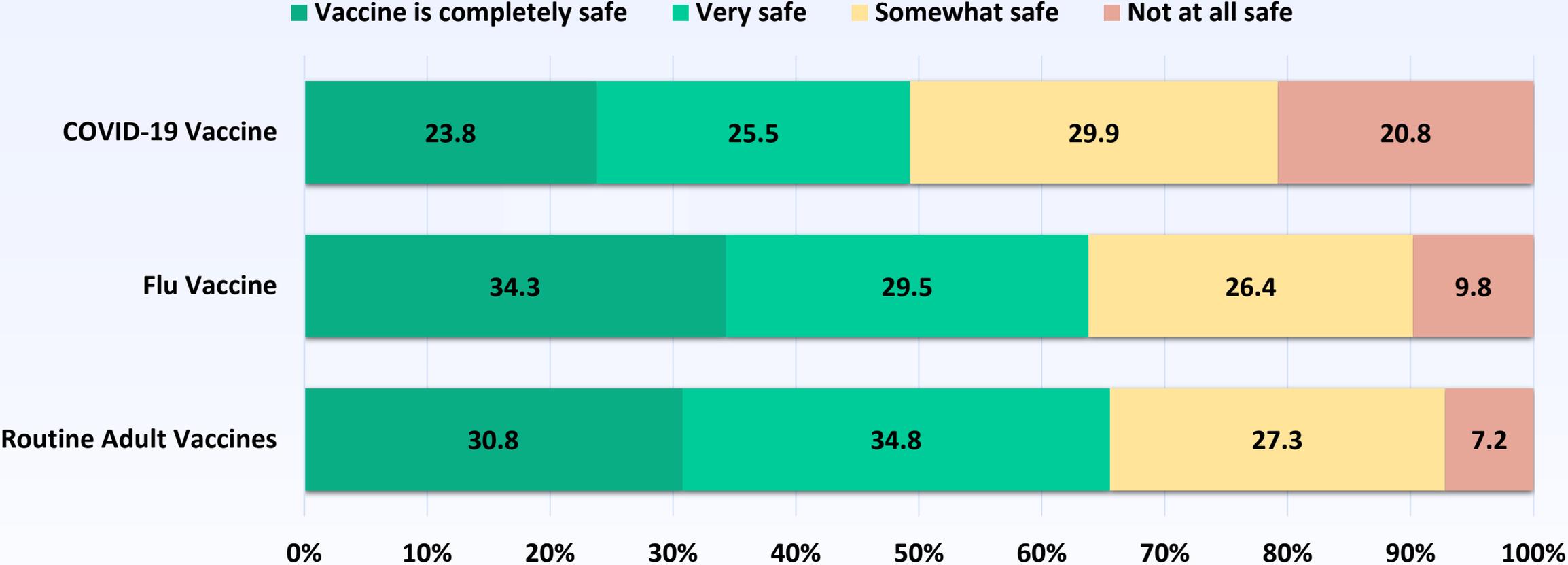
A nationally representative sample of U.S. adults aged 18 years and older

Top concerns or issues regarding bivalent COVID-19 vaccine, June 2023

	Received 1+ doses of COVID-19 vaccine but not the bivalent vaccine	Unvaccinated with any COVID-19 vaccine
Definitely will	<ul style="list-style-type: none"> • Too busy or kept forgetting (36.3%) 	Omitted (N<30)
Probably will or unsure	<ul style="list-style-type: none"> • Had enough vaccines (27%) • Too busy or kept forgetting (22.2%) • No provider recommendation (19.8%) • Unknown serious side effects (12.8%) 	<ul style="list-style-type: none"> • Unknown serious side effects (37.1%)
Probably or definitely will NOT	<ul style="list-style-type: none"> • Unknown serious side effects (43.1%) • Had enough vaccines (42.4%) • Not enough studies (33.8%) • Do not trust gov't/pharma (30%) • Effectiveness (29.8%) • Heart-related issues (28.6%) 	<ul style="list-style-type: none"> • Unknown serious side effects (56.5%) • Do not trust gov't/pharma (50.5%) • Not enough studies (47.1%) • Heart-related issues (39.6%) • Effectiveness (36.1%)

A nationally representative sample of U.S. adults aged 18 years and older

Confidence in vaccine safety is higher for influenza and other routine adult vaccines than for COVID-19 vaccine, June 2023

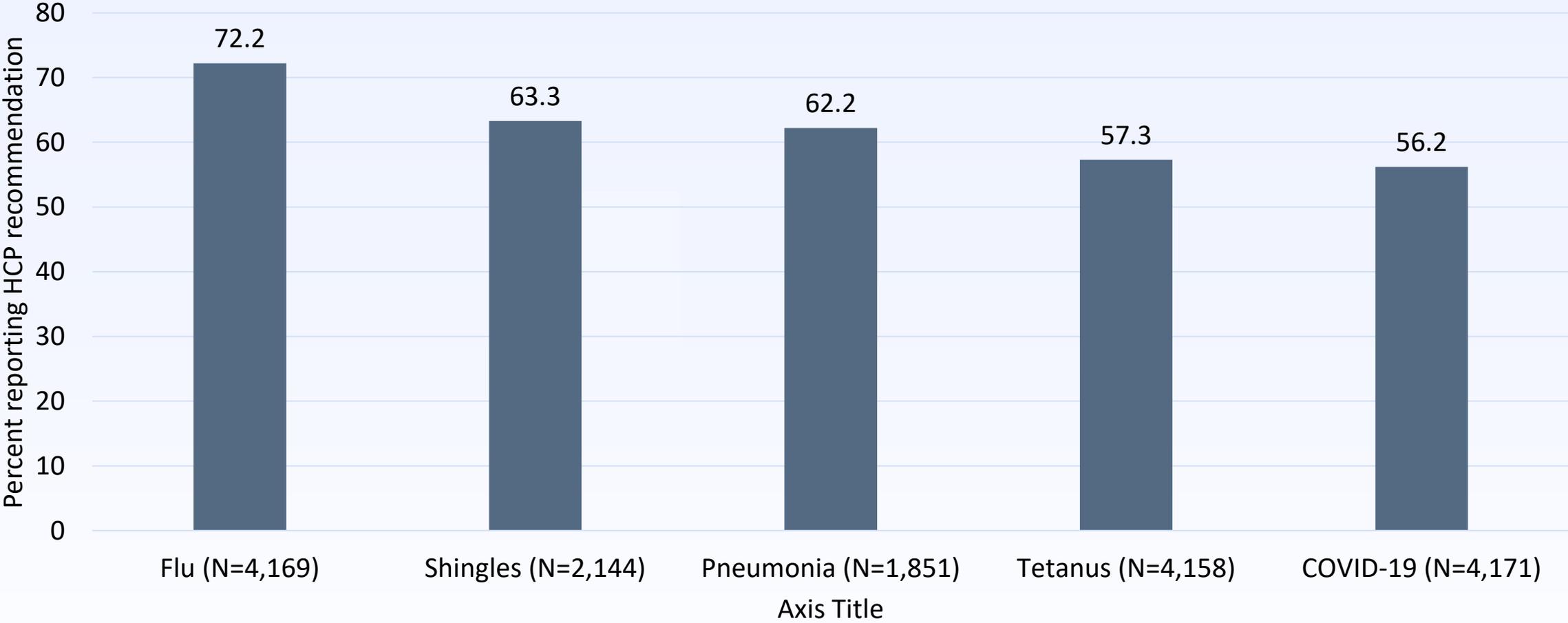


Analysis limited to those who responded to all three survey questions (N=4,164). Omitted category of respondents who answered “not sure” is <1%.

A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from June 2023 (N=4,214), unpublished data

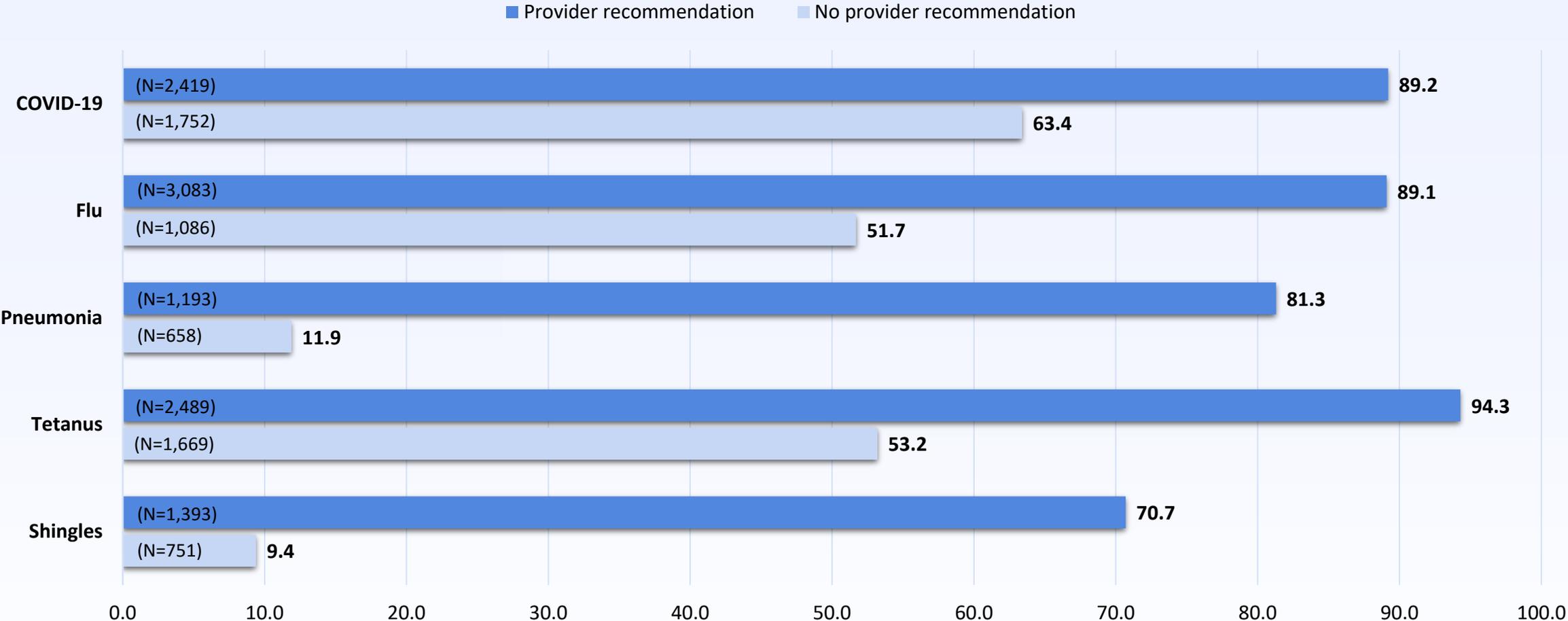
Vaccine recommendation by healthcare provider (among those eligible to receive the vaccine), June 2023



A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from June 2023 (N=4,214), unpublished data

Vaccine receipt by healthcare provider recommendation (among those eligible to receive the vaccine), June 2023



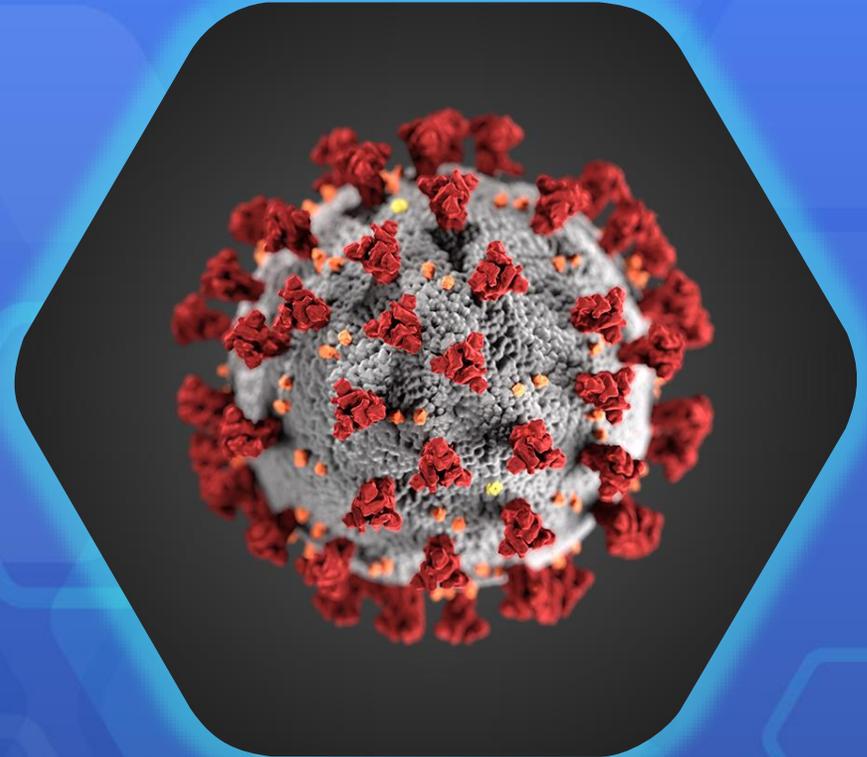
A nationally representative sample of U.S. adults aged 18 years and older

COVID-19 vaccine recommendation and administration by U.S. health care providers among women of reproductive age

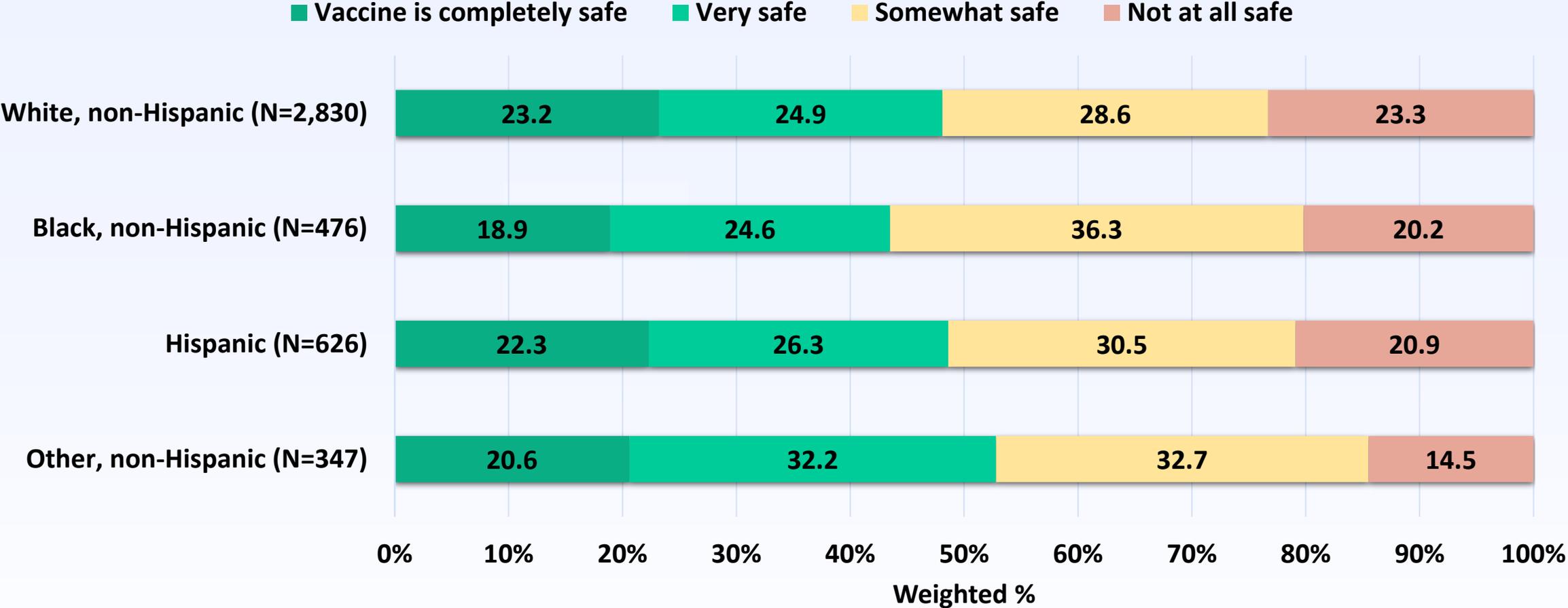
- Data from the Fall 2022 DocStyles survey were analyzed to examine the prevalence of COVID-19 vaccination attitudes and practices among health care providers (HCPs) caring for women of reproductive age, and to assess whether providers recommended and offered or administered the COVID-19 vaccines to their pregnant patients
- Overall, **82.9%** of providers reported recommending COVID-19 vaccination to women of reproductive age, and **54.7%** offered or administered the vaccine in their practice
- Among HCPs who cared for pregnant patients, obstetrician-gynecologists were more likely to recommend COVID-19 vaccination to pregnant patients (**94.2%**) than were family practitioners/internists (**82.1%**)
- HCPs were more likely to offer or administer COVID-19 vaccination onsite to pregnant patients if they also offered or administered influenza and Tdap vaccines

Domain Equity Question:

Is the intervention equally acceptable across all populations?



COVID-19 vaccine safety confidence by race and ethnicity, August 2023

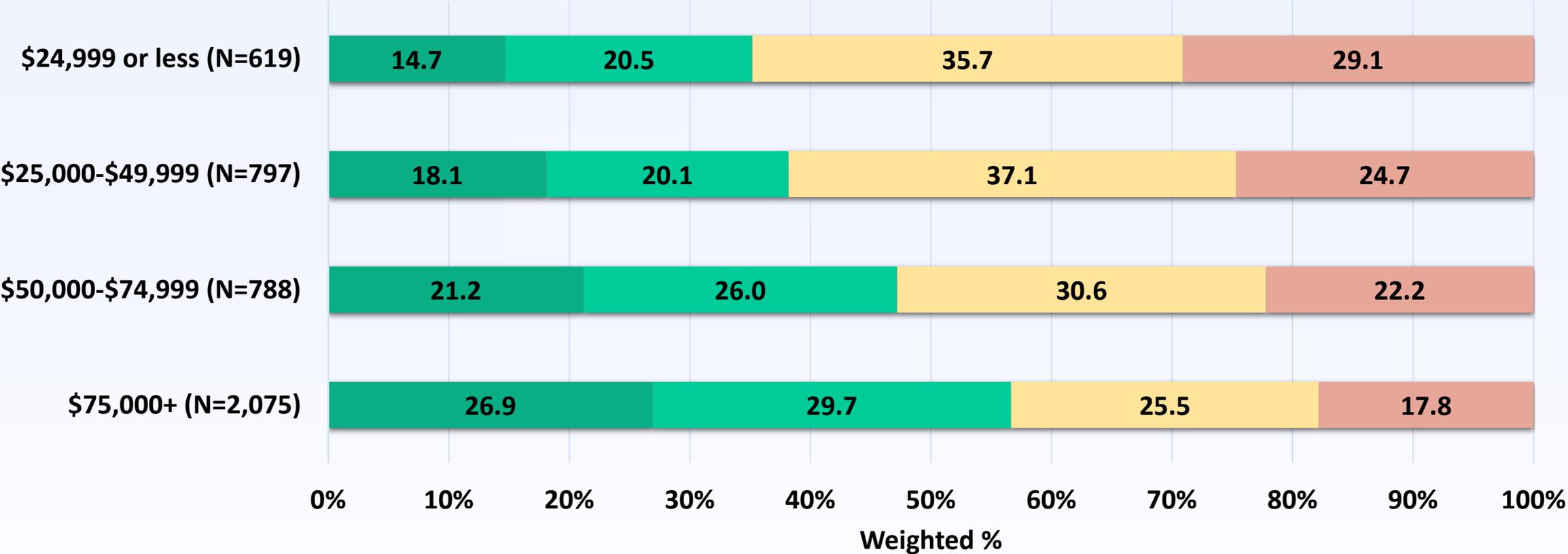


A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

COVID-19 vaccine safety confidence by income, August 2023

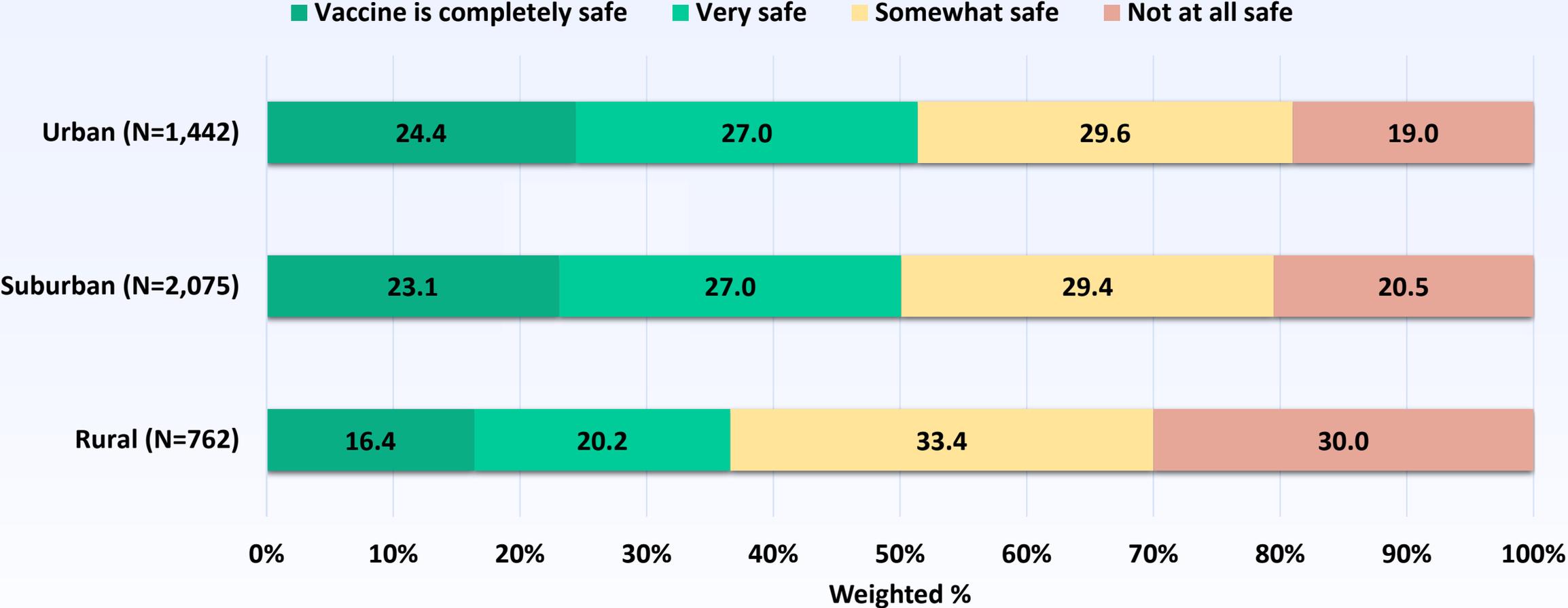
■ Vaccine is completely safe
 ■ Very safe
 ■ Somewhat safe
 ■ Not at all safe



A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

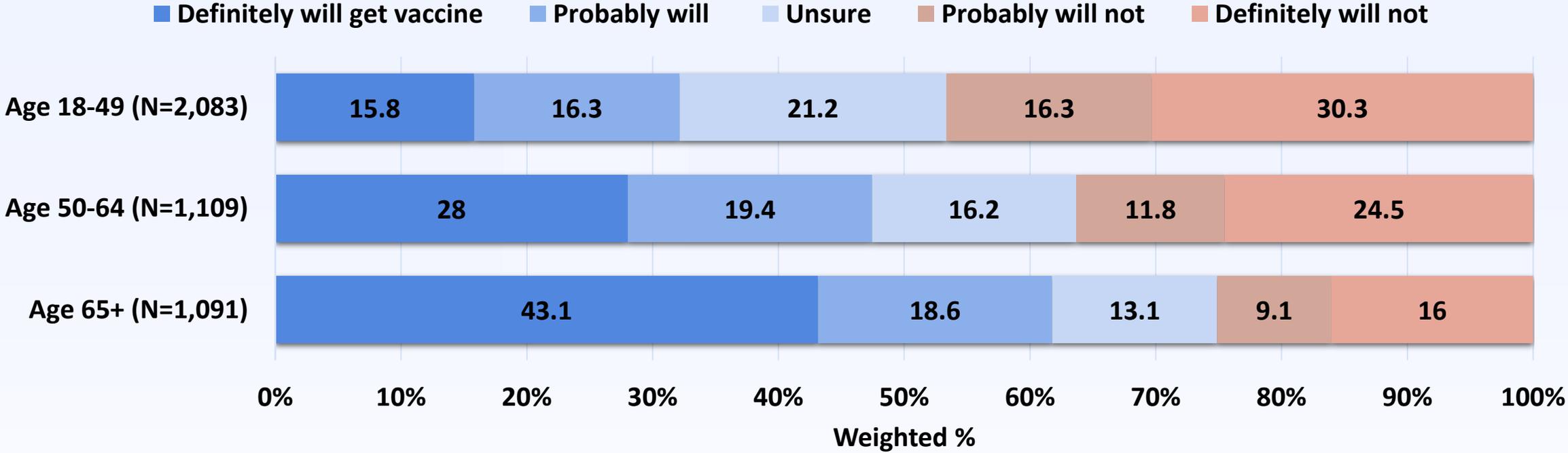
COVID-19 vaccine safety confidence by urbanicity, August 2023



A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Intent to get new, updated COVID-19 vaccine by age, August 2023



A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

Percent of people receiving COVID-19 vaccine by age

December 14, 2020 – May 10, 2023*

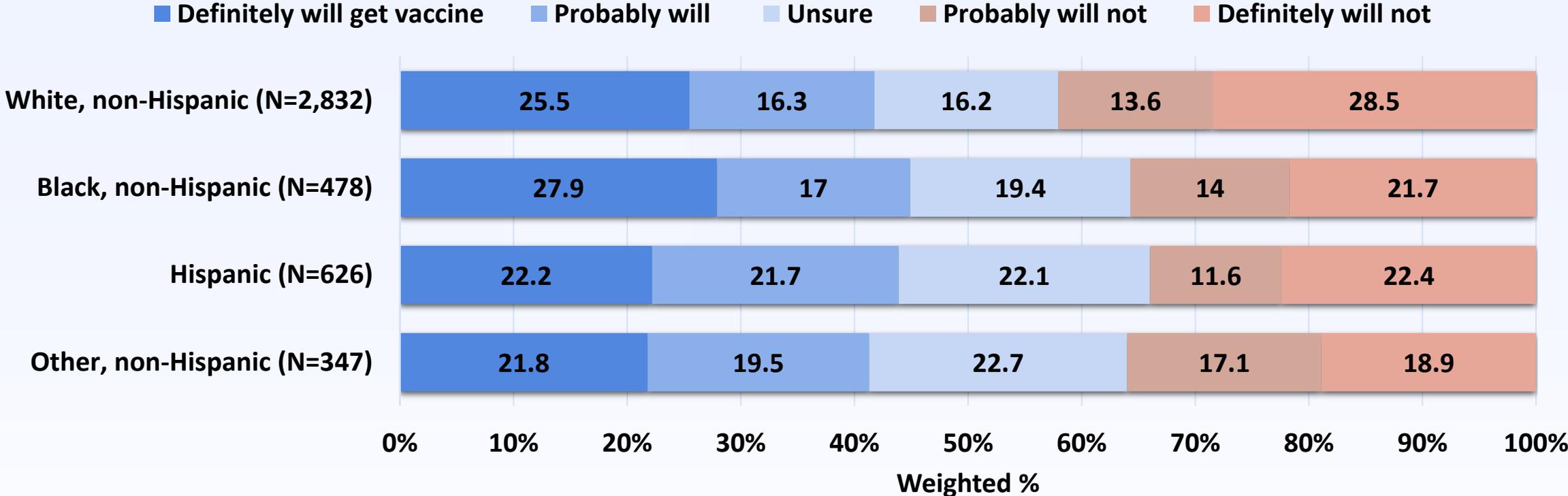
	<2 yrs	2-4 yrs	5-11 yrs	12-17 yrs	18-24 yrs	25-49 yrs	50-64 yrs	+65 yrs
At Least One Dose	8.9%	10.9%	40.0%	72.2%	82.3%	85.5%	95.0%	95.0%
Completed Primary Series	4.7%	6.1%	32.9%	61.8%	66.8%	72.2%	83.8%	94.4%
Updated (Bivalent) Booster Dose	0.6%	0.6%	4.8%	7.8%	7.4%	12.1%	21.7%	43.3%

*Data cutoff on May 10, 2023 is due to the end of the Public Health Emergency (PHE) on May 11, 2023

Data source: VTrcks, IIS, Federal Pharmacy Program, Federal Entities Program, U.S. Census Bureau 10-year July 2019 National Population Estimates

<https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>. Accessed 9/5/2023

Intent to get new, updated COVID-19 vaccine by race and ethnicity, August 2023



A nationally representative sample of U.S. adults aged 18 years and older

IPSOS KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, results from August 2023 (N=4,299), unpublished data

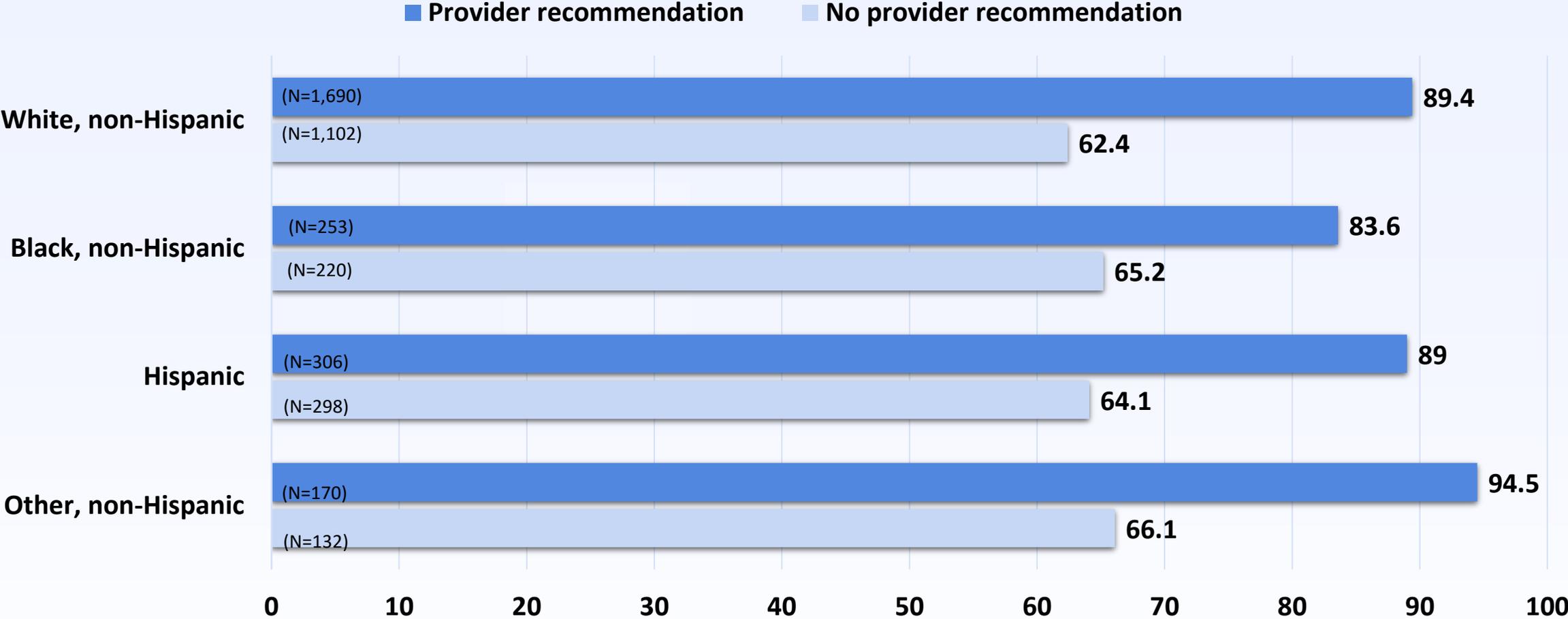
Estimated percent of people ≥ 18 years reporting COVID-19 vaccination by race/ethnicity

National Immunization Survey Adult COVID Module, April 22, 2021 – March 25, 2023

	AI/AN, NH	Asian, NH	Black, NH	Hispanic/Latino	NHOPI, NH	White, NH
At Least One Dose	81.0%	98.2%	89.2%	89.1%	83.5%	87.0%
Completed Primary Series	75.8%	97.2%	85.1%	84.0%	82.6%	84.3%
Updated (Bivalent) Booster Dose Among Adults with a Completed Primary Series	28.5%	36.3%	29.3%	25.6%	18.6%	37.5%

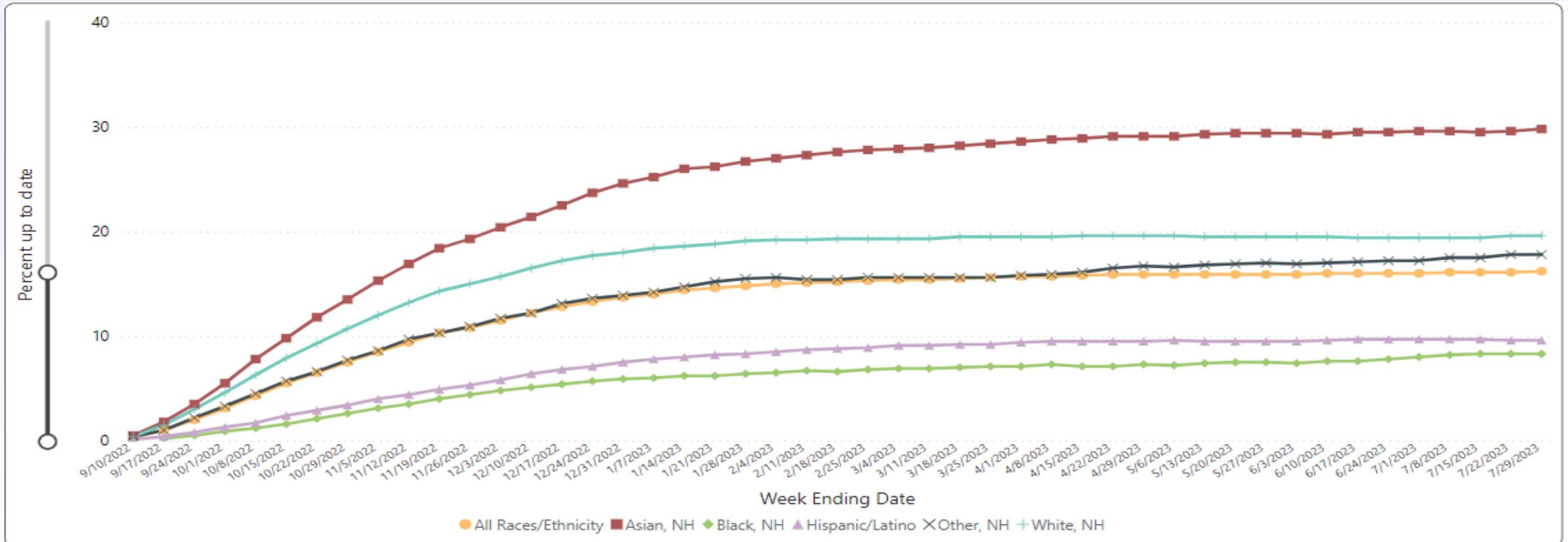
Source: National Immunization Survey Adult COVID Module. <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>. Accessed 9/5/2023

COVID-19 vaccine receipt by healthcare provider recommendation by race and ethnicity, June 2023



A nationally representative sample of U.S. adults aged 18 years and older

Percent of pregnant people ages 18-49 years who are up to date* with COVID-19 vaccines overall and by race and ethnicity – Vaccine Safety Datalink, September 1, 2022 – July 29, 2023



*Up to date is defined as the percent of pregnant people who received an updated bivalent dose before or during pregnancy, with the denominator including those pregnant at least 1 day during the specified month ending date, and the numerator including those who received an updated bivalent dose. CDC recommended bivalent boosters to persons age ≥12 years starting September 1, 2022. Data on bivalent boosters among pregnant persons was available starting September 4, 2022, and includes doses received starting September 1, 2022

CDC. COVID-19 vaccination among pregnant people aged 18-49 years overall, by race and ethnicity, and date reported to CDC – Vaccine Safety Datalink,* United States.

<https://covid.cdc.gov/covid-data-tracker/#vaccinations-pregnant-women> Accessed August 9, 2023

Summary

Acceptability

- Vaccine receipt varies by age and race/ethnicity
- Fall vaccination intent increases with increasing age; those ages 65+ have the highest percentage reporting they “definitely” or “probably” will get the vaccine compared to other age groups
- Confidence in COVID-19 vaccine safety differs across the population
- Compared to other vaccines, COVID-19 vaccines were recommended the least by health care providers
- Those who received a provider recommendation overall and by race and ethnicity were more likely to receive the recommended vaccine
- Encouraging health care providers to recommend, offer, and administer COVID-19 vaccines, could help reinforce vaccine confidence and increase coverage¹

Acceptability

Is the 2023 – 2024 COVID-19 vaccine acceptable to key stakeholders?

- Are there key stakeholders that would not accept the distribution of benefits and harms?
- Are there key stakeholders that would not accept the undesirable effects in the short term for the desirable effects (benefits) in the future?

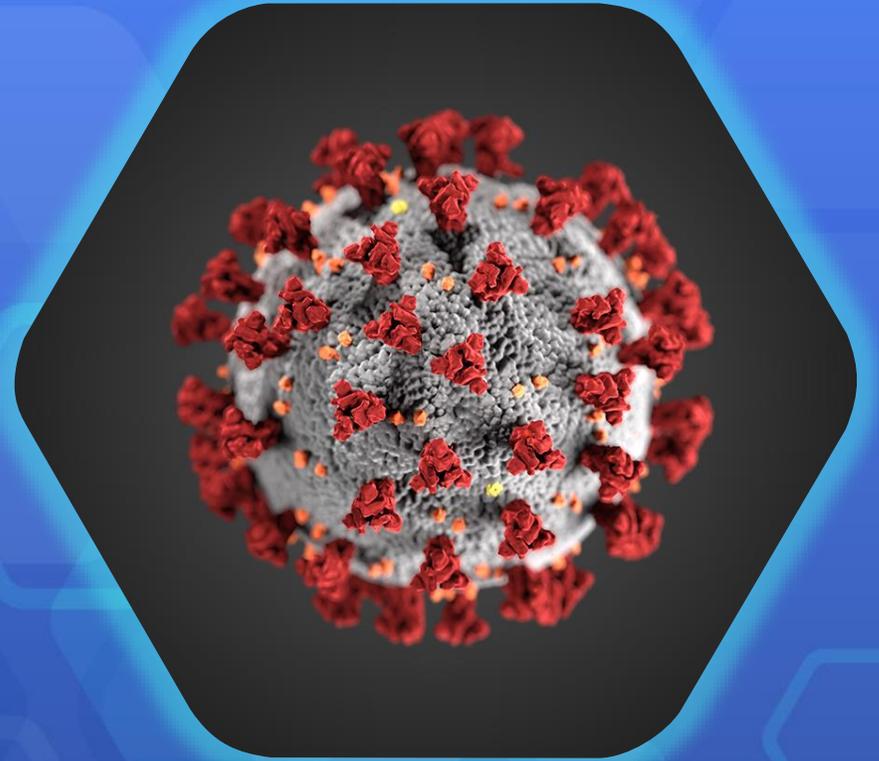
No Probably no Probably yes Yes Varies Don't know

Majority opinion

Minority opinion

EtR Domain:

Feasibility



Fall COVID-19 vaccine transition

- Vaccines with a monovalent XBB.1.5 composition will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the United States Government (USG)
- The public will continue to be directed to [Vaccines.gov](https://www.vaccines.gov) to find providers offering COVID-19 vaccine
- While providers will no longer be required to report inventory to Vaccines.gov after vaccines transition to being available on the commercial market, they will continue to be encouraged to report voluntarily
 - Providers are also strongly encouraged to report the minimum age (in months and years) for whom a location can administer vaccine
- CDC will continue its efforts to make sure that all people have access to COVID-19 medical countermeasures and know where to find product now and in the future

Feasibility of vaccine implementation

- Inclusion of COVID-19 vaccines in Vaccines for Children (VFC) will likely result in more pediatricians stocking the vaccine
- There will be single dose vial presentations and smaller minimum order quantities
 - Directly addresses concerns from health care providers (HCPs), likely to reduce wastage, eases logistics and helps with storage capacity limitations
 - Moderna, 12+ years: single dose vial (10-pack) and manufacturer-prefilled syringes (10-pack)
 - Moderna, 6 months – 11 years: single dose vial (10-pack)
 - Novavax, 12+ years: 5-dose multi-dose vial (2 vials per carton)
 - Pfizer, 12+ years: single dose vial (10-pack), limited quantity of manufacturer-prefilled syringes (10-pack)
 - Pfizer, 5 – 11 years: single dose vial (10-pack)
 - Pfizer, 6 months – 4 years: 3-dose multi-dose vial (10-pack)
- Preparation is the same or simpler than it was before
 - Moderna preparation is the same (no dilution)
 - Novavax preparation is the same (no dilution)
 - Pfizer preparation is simplified (currently 2 presentations require dilution; for 2023 – 2024 COVID-19 vaccine, ONLY little peds formulation require dilution)

Feasibility of vaccine implementation, cont'd

- Storage and handling will be the SAME as it is now
 - Moderna: Frozen until expiration; 30 days at refrigerator storage
 - Novavax: Stable at 2-8°C (refrigerator storage); 9-month shelf life; use within 12 hours of first puncture
 - Pfizer: Ultra-cold storage until expiration; 10 weeks at refrigerator storage
 - Ultra-cold storage continues to be a challenge; most provider offices do not have a unit
- Dose volume for Pfizer is simplified (all doses are 0.3mL)
- Moderna now only has two presentations, reducing the chance for errors

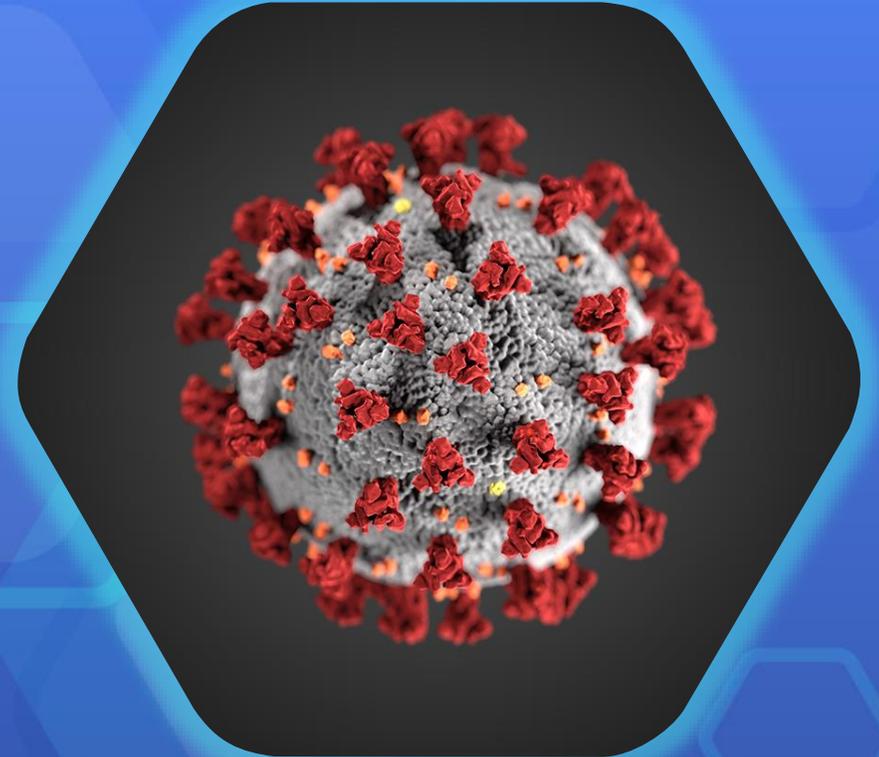
Barriers to implementation

- There are now THREE seasonal vaccines and preventative products¹ for respiratory diseases to manage
 - More seasonal vaccines to manage
 - Limited storage space and more vaccines
 - More opportunities for vaccine administration errors
- Providers have to adapt to new cap/label colors
 - Moderna: 6 months – 11 years is **blue** cap/**green** label; 12+ years is **blue** cap/**blue** label
 - Novavax: 12+ is **blue**
 - Pfizer: 6 months – 4 years is **yellow**; 5 – 11 years is **blue**; 12+ years is **gray**
- Moderna, Novavax and Pfizer all have products with blue caps, introducing opportunity for error

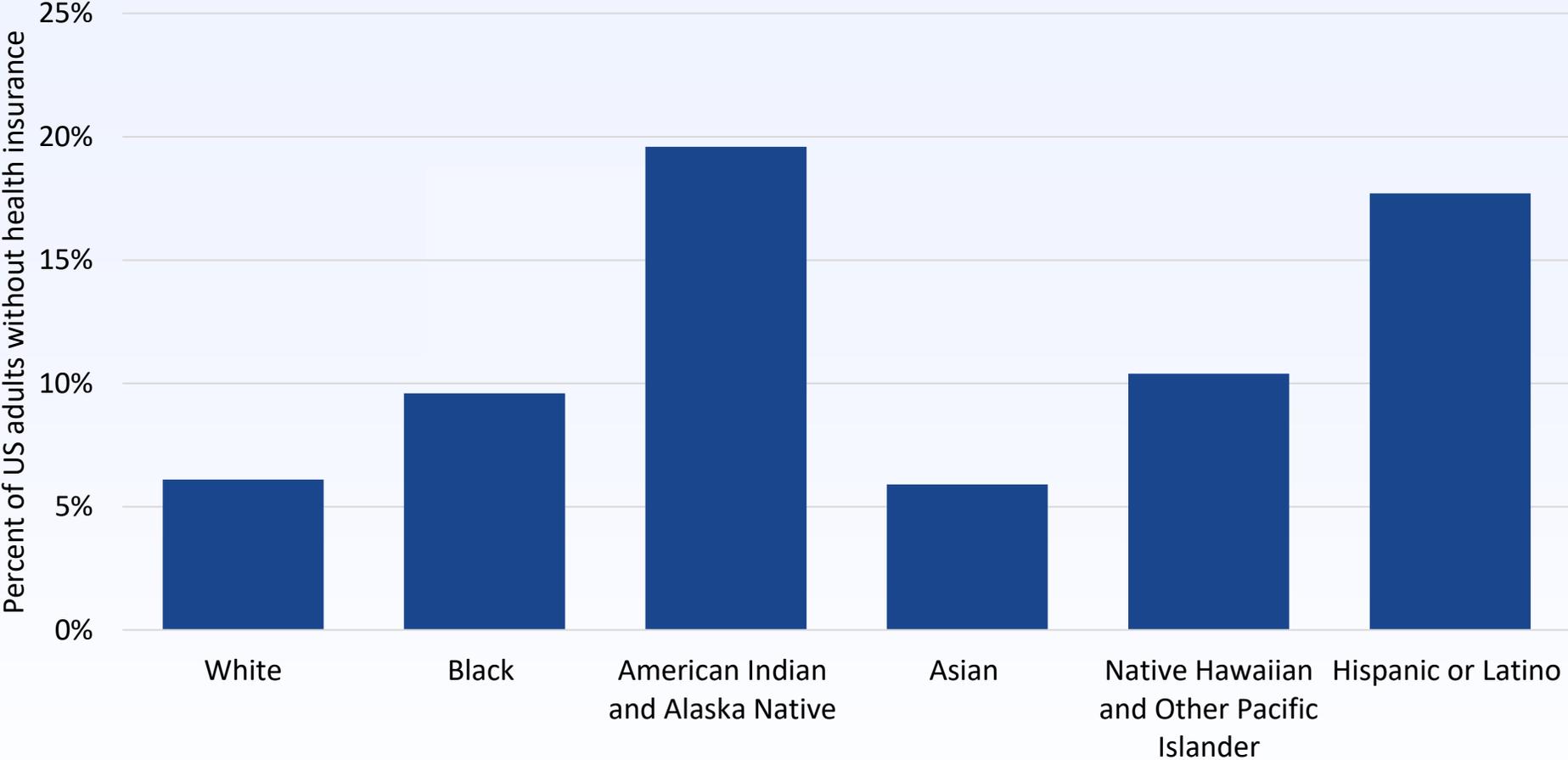
¹ COVID-19 vaccine, Influenza vaccine, RSV vaccine, and nirsevimab, a long-acting monoclonal antibody for RSV prevention in infants
Immunization Services Division, internal planning documents

Domain Equity Question:

Is the intervention equally feasible to implement across all populations?



There are disparities in uninsured status that could impact who gets a COVID-19 vaccine



CDC vaccine programs for people who are uninsured

- CDC will provide access to COVID-19 vaccines for uninsured individuals once COVID-19 vaccines become commercially available¹
- Uninsured children will be able to receive COVID-19 vaccines through the existing Vaccines for Children (VFC) program¹
 - The VFC program offers vaccines at no low or no cost to eligible children through a national network of participating health care providers²
- Adults who are uninsured or underinsured will be able to receive no-cost COVID-19 vaccines through the temporary Bridge Access Program for COVID-19 Vaccines. This program consists of two components:
 - Public health infrastructure: through state immunization programs, State and local health departments and HRSA-supported health centers will provide no-cost COVID-19 vaccines to adults who are uninsured or underinsured
 - Participating retail pharmacies: CVS, Walgreens, and eTrueNorth will continue to provide no-cost COVID-19 vaccines to adults who are uninsured or underinsured³

1. CDC. HHS Commercialization Transition Guide: Sunsetting the US Government COVID-19 Vaccine Distribution Program. <https://www.cdc.gov/vaccines/covid-19/downloads/HHS-Commercialization-Transition-Guide-508.pdf> Accessed August 4, 2023

2. CDC. VFC Information for Parents. <https://www.cdc.gov/vaccines/programs/vfc/parents/index.html> Accessed August 30, 2023

3. CDC. Bridge Access Program for COVID-19 Vaccines. <https://www.cdc.gov/vaccines/programs/bridge/index.html> Accessed September 7, 2023

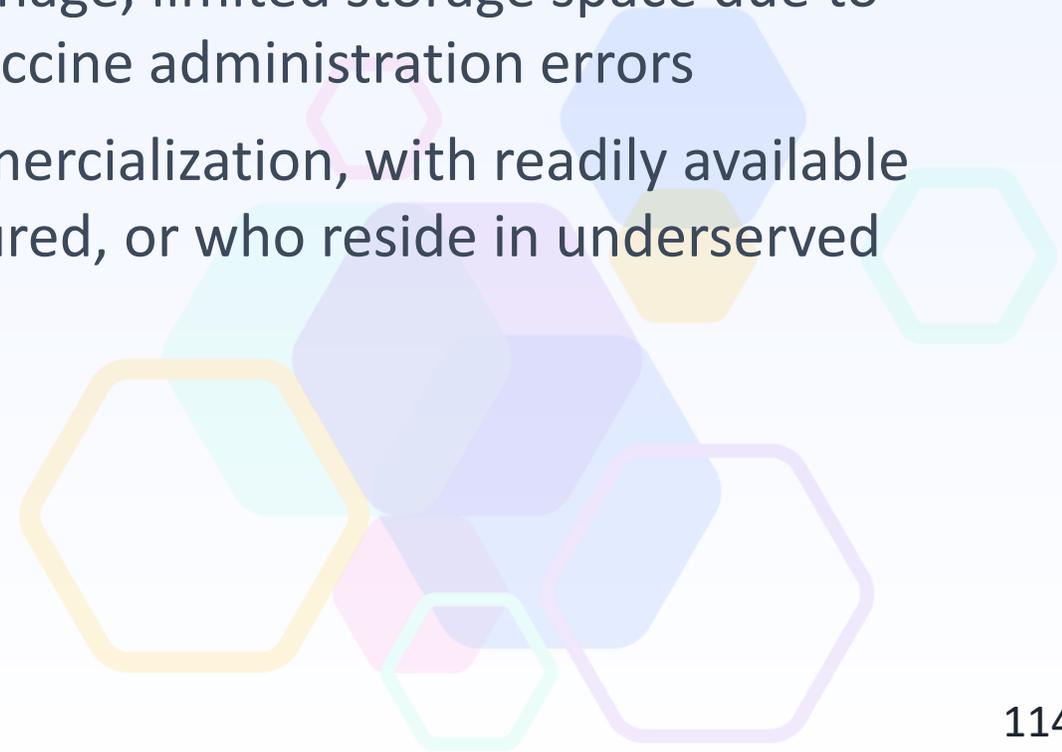
Availability of vaccines in underserved communities

- CDC's Bridge Access Program for COVID-19 Vaccines and COVID-19 vaccine implementation plans are intentionally designed to overcome barriers to access and availability
 - This includes design for maximized proximity to no-cost COVID-19 vaccines among populations of people who are uninsured or underinsured
- CDC and HHS continue to invest in health systems and programs that support vaccine access and outreach in underserved communities – such as HRSA-Supported Health Centers, Rural Health Clinics, and State and local health departments
 - These networks can be leveraged for access to COVID-19 vaccines as well as other needed medicines

Summary

Feasibility

- Implementation of the 2023 – 2024 COVID-19 vaccine will likely reduce wastage, ease logistics, help with storage capacity limitations and reduce the chance of errors
- Nevertheless, there will be now be three seasonal vaccines for respiratory diseases, in which there will be more seasonal vaccines to manage, limited storage space due to additional vaccines and more opportunities for vaccine administration errors
- Vaccines will continue to be accessible after commercialization, with readily available resources for those who are uninsured, underinsured, or who reside in underserved communities



Feasibility

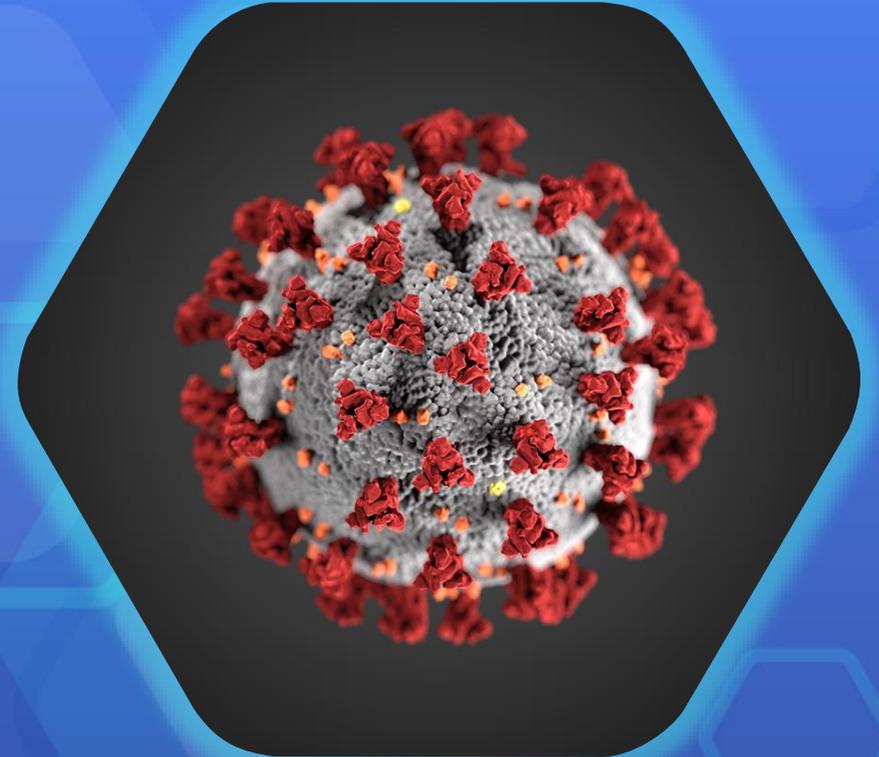
Is the 2023 – 2024 COVID-19 vaccine feasible to implement among populations currently recommended for a dose?

- Is the 2023 – 2024 COVID-19 vaccine program sustainable?
- Are there barriers that are likely to limit the feasibility of implementing the 2023 – 2024 COVID-19 vaccine or require considerations when implementing it?
- Is access to the 2023 – 2024 COVID-19 vaccine an important concern?

No **Probably no** **Probably yes** **Yes** **Varies** **Don't know**

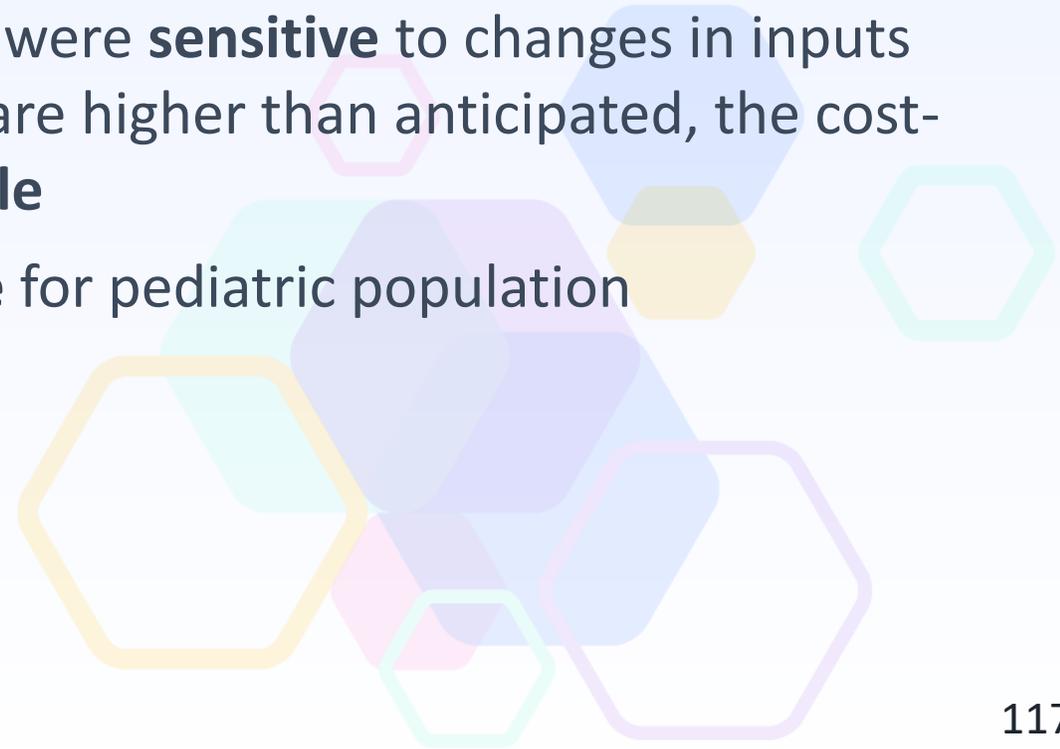
EtR Domain:

Resource Use



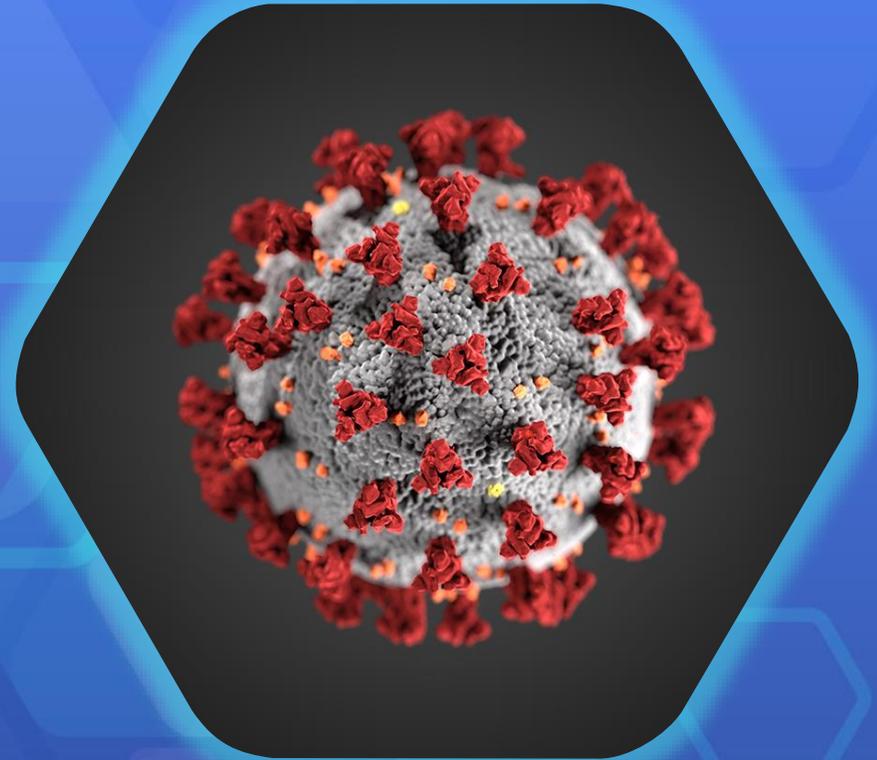
Summary

- COVID-19 vaccination is a cost – effective intervention, particularly in persons ages ≥ 65 years in which the vaccine is **cost saving**
- Cost-effectiveness estimates in those ages ≥ 50 years were **robust** to input changes across plausible ranges
- Cost-effectiveness estimates in those 18-49 years were **sensitive** to changes in inputs
 - If vaccine effectiveness or hospitalization rates are higher than anticipated, the cost-effectiveness estimates would be **more favorable**
- Cost-effectiveness estimates are **not yet available** for pediatric population



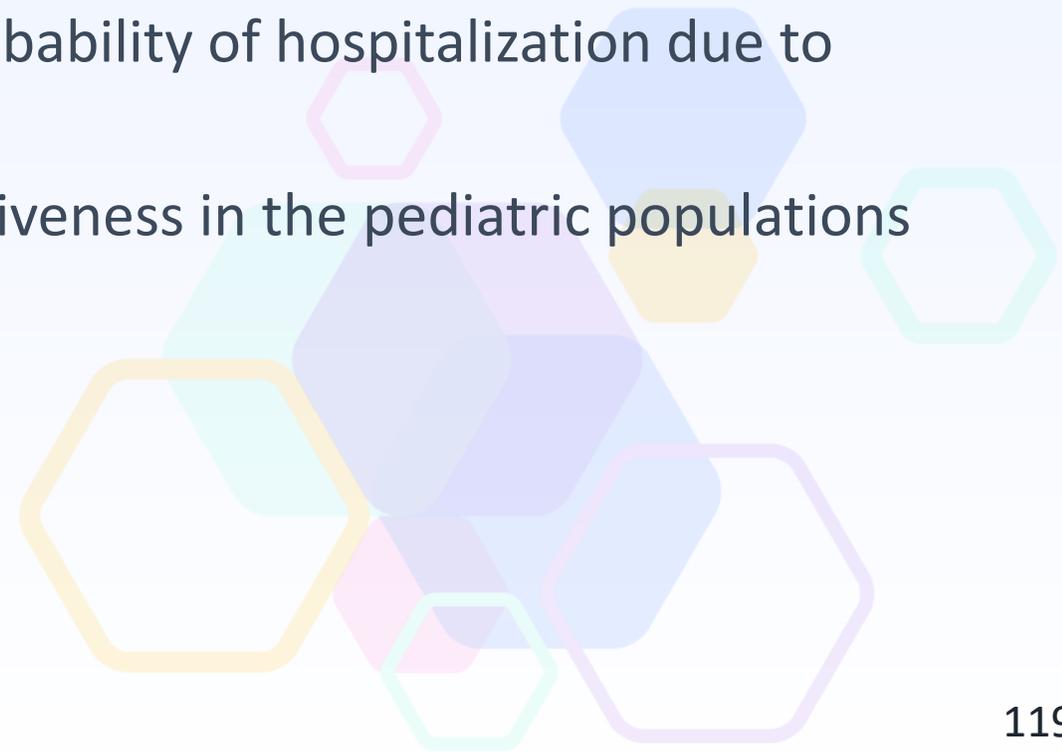
Domain Equity Question:

Is the intervention a reasonable and efficient allocation of resources across all populations?



Is the intervention a reasonable and efficient allocation of resources across all populations?

- COVID-19 vaccination is **most cost-effective** in older adults in which disease burden is highest compared to younger adults
- COVID-19 vaccination is **likely more cost-effective** in populations with risk factors, such as underlying conditions, which increase their probability of hospitalization due to COVID-19
- Additional work is ongoing to evaluate cost-effectiveness in the pediatric populations



Resource Use

Is the 2023 – 2024 COVID-19 vaccine a reasonable and efficient allocation of resources?

- What is the cost-effectiveness of the 2023 – 2024 COVID-19 vaccine?
- How does the cost-effectiveness of the 2023 – 2024 COVID-19 vaccine change in response to changes in context, assumptions, etc.?

No Probably no Probably yes Yes Varies Don't know

Majority opinion

Minority opinion

The background features a blue gradient with various hexagonal shapes in different shades of blue and white, some overlapping and some as outlines.

Summary and Work Group Interpretations

Summary and Work Group Interpretation: Public Health Burden

- The burden of COVID-19 varies by age and underlying condition status with those ages **≥65 years** and those with **multiple underlying conditions** having the **highest risk** of severe outcomes due to COVID-19
- COVID-19 burden is **currently lower** than at previous points in the pandemic, however there are still **thousands** of hospitalizations and **hundreds** of deaths each week
- Children and adults ages 5 – 49 years had the lowest hospitalization rates overall
 - Severe outcomes occur in this age group, including in people with **no underlying medical conditions**
- Although hospitalization rates are currently low, we have seen rates increase in recent weeks and **anticipate further increases** as we enter respiratory virus season
- Majority of U.S. population has some level of **immunity** due to infection, vaccination, or both
 - Vaccine and infection-induced immunity **wane** and **new variants** have emerged, suggesting that susceptibility remains and may increase over time
- Racial and ethnic minority groups have been disproportionately affected by COVID-19

Summary and Work Group Interpretation: Benefits and Risks

- Monovalent XBB containing COVID-19 vaccines **increase the immune response** against the currently circulating variants
- Last year's updated vaccine was **effective** at preventing medically attended COVID-19, hospitalization due to COVID-19, and death due to COVID-19
- COVID-19 vaccines have a **high degree** of safety
 - Unlikely that updating the formulation would increase adverse event rates
- **Benefits** are anticipated in all age groups; benefits of COVID-19 vaccines vary by **age**, and incidence of COVID-19 hospitalizations
- **Benefits outweigh risks** in age groups for which there is a risk of myocarditis
- Modeling projects **more hospitalization and deaths averted** when updated doses are **universally recommended** compared to no recommendation or recommended only for persons ≥ 65 years

Summary and Work Group Interpretation: Considerations Regarding a Universal vs. Non-universal Policy

- Work Group considered non-universal policy options, with considerable discussion around the magnitude of benefits in the young, healthy population
- As part of these deliberations, Work Group requested additional data on severe illness due to COVID-19 in those with and without underlying conditions
 - No group that clearly had no risk of severe illness
 - The vast majority of the US population has an underlying condition that would qualify under a risk based recommendation
 - Prevalence of overweight and obesity alone is >70% of adults¹
 - Risk based recommendation would not allow access to COVID-19 vaccines for all that wanted them
- Shared clinical decision making could create barriers to vaccination and may not effectively target those at highest risk
- COVID-19 epidemiology remains uncertain and non-universal recommendations would need to be quickly revisited if there was an increase in burden
- Still substantial COVID-19 disease burden and simple, stable recommendations may increase vaccine coverage over time
- Work Group emphasized that COVID-19 recommendations should be reviewed on an ongoing basis as more is learned about COVID-19 seasonality and disease burden in the future

¹National Health Statistics Reports; <https://stacks.cdc.gov/view/cdc/106273>

Summary and Work Group Interpretation: COVID-19 vaccine recommendations for children

- Burden of severe illness due to COVID-19 is **lowest** among children ages 5 – 17 years
- Despite lower burden relative to other age groups, **hundreds** of deaths due to COVID-19 occurred in this age group in 2021 and 2022
 - **Half** of pediatric COVID-19 deaths were in individuals with **no underlying conditions**
- Number of COVID-19 hospitalizations and deaths in this age group are **comparable** to the burden seen in other vaccine preventable diseases for which there are universal recommendations
- **Potential additional benefits of vaccination**, such as prevention of post-COVID conditions and potential for reduced school absenteeism
- Risk of myocarditis appears **lower** than the risk observed following primary series doses
 - Potentially lower due to increased interval between doses
 - Certainty is limited by relatively lower sample size of booster recipients in VSD
- Future COVID-19 epidemiology remains **uncertain** and the low disease burden we are currently seeing may not last
- After a robust discussion, Work Group was supportive of a universal recommendation **at this time**

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 of public health importance?	Yes
Benefits and Harms	How substantial are the desirable anticipated effects?	Large
	How substantial are the undesirable anticipated effects?	Small
	Do the desirable effects outweigh the undesirable effects?	Favors intervention
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Moderate
	Is there important variability in how patients value the outcomes?	Probably important uncertainty or variability
Acceptability	Is the 2023-2024 COVID-19 vaccine acceptable to key stakeholders?	Yes / Probably yes / Varies
Feasibility	Is the 2023-2024 COVID-19 vaccine feasible to implement?	Yes
Resource Use	Is the 2023-2024 COVID-19 vaccine a reasonable and efficient allocation of resources?	Yes

Evidence to Recommendations Framework

Summary: Work Group Interpretations

Balance of consequences	Undesirable consequences <i>clearly outweigh</i> desirable consequences in most settings	Undesirable consequences <i>probably outweigh</i> desirable consequences in most settings	The balance between desirable and undesirable consequences is <i>closely balanced or uncertain</i>	Desirable consequences <i>probably outweigh</i> undesirable consequences in most settings	Desirable consequences <i>clearly outweigh</i> undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences
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Majority opinion

Minority opinion

Evidence to Recommendations Framework

Summary: Work Group Interpretations

Type of recommendation	We do not recommend the intervention	We recommend the intervention for individuals based on shared clinical decision-making	We recommend the intervention
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Proposed ACIP Voting Language

ACIP recommends 2023–2024 (monovalent, XBB containing) COVID-19 vaccines as authorized under Emergency Use Authorization (EUA) or approved by Biologics License Application (BLA) in persons ≥ 6 months of age

Clinical Considerations

Proposed 2023 – 2024 mRNA COVID-19 vaccine recommendations:

- Everyone ages 5 years and older is recommended to receive 1 dose of a 2023–2024 mRNA COVID-19 vaccine
- Children ages 6 months–4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer-BioNTech mRNA COVID-19 vaccine) with at least one dose of the 2023–2024 COVID-19 vaccine¹
- People who are moderately or severely immunocompromised should complete a 3-dose initial series with at least one dose of the 2023–2024 COVID-19 vaccine and may receive 1 or more additional 2023–2024 COVID-19 vaccine doses²
- Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States

1. Children ages 6 months – 4 years that previously received a single dose of Pfizer-BioNTech vaccine should receive 2 doses of Pfizer-BioNtech vaccine.

2. Additional details in the interim clinical considerations

Key changes from bivalent mRNA recommendations

Bivalent recommendations	Proposed 2023 – 2024 vaccine recommendations	Rationale
Everyone ages 6 years and older recommended for a single bivalent dose	Everyone ages 5 years and older recommended for a single 2023 – 2024 dose	Eliminates complex recommendations for 5-year-olds
Two Moderna dosages authorized for 6 months – 5 years, depending on vaccination history and immune status	All Moderna doses in ages 6 months – 11 years are now 25 µcg	Reduces the number of COVID-19 vaccine products in use
Optional 2 nd bivalent dose for those ages 65 years and older	No additional dose recommendation at this time	Will monitor epidemiology and vaccine effectiveness to determine if additional doses are needed

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- Sierra Scarbrough
- Amadea Britton
- Jefferson Jones
- Aron Hall
- Barbara Mahon
- COVID-NET
- COVID-19 Scenario Modeling Hub
- University of Michigan COVID-19 Vaccination Modeling Team
- Immunization Safety Office
- Immunization Services Division
- Coronavirus and other Respiratory Viruses Division
- National Center for Immunization and Respiratory Diseases

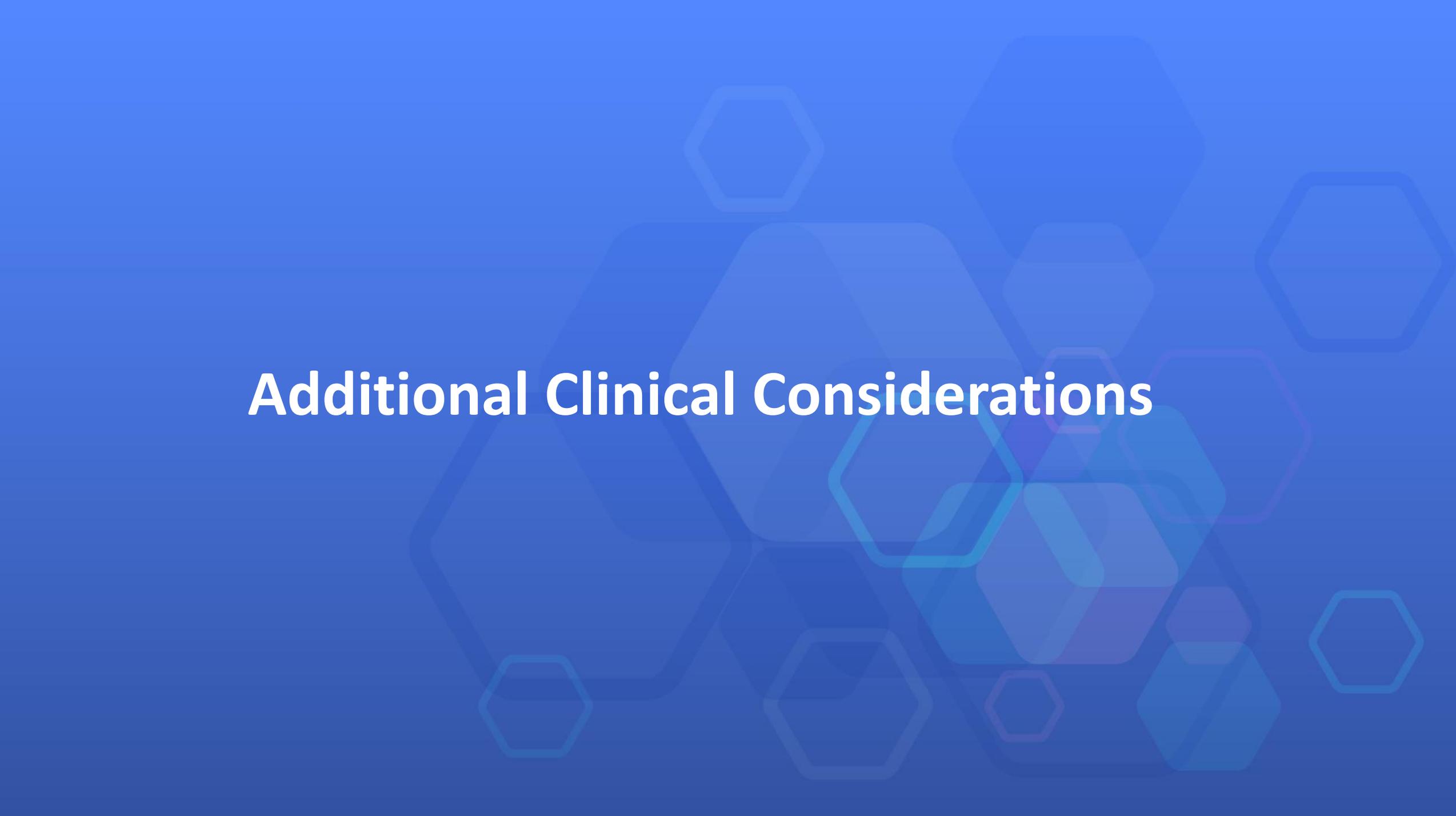
Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

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Additional Clinical Considerations

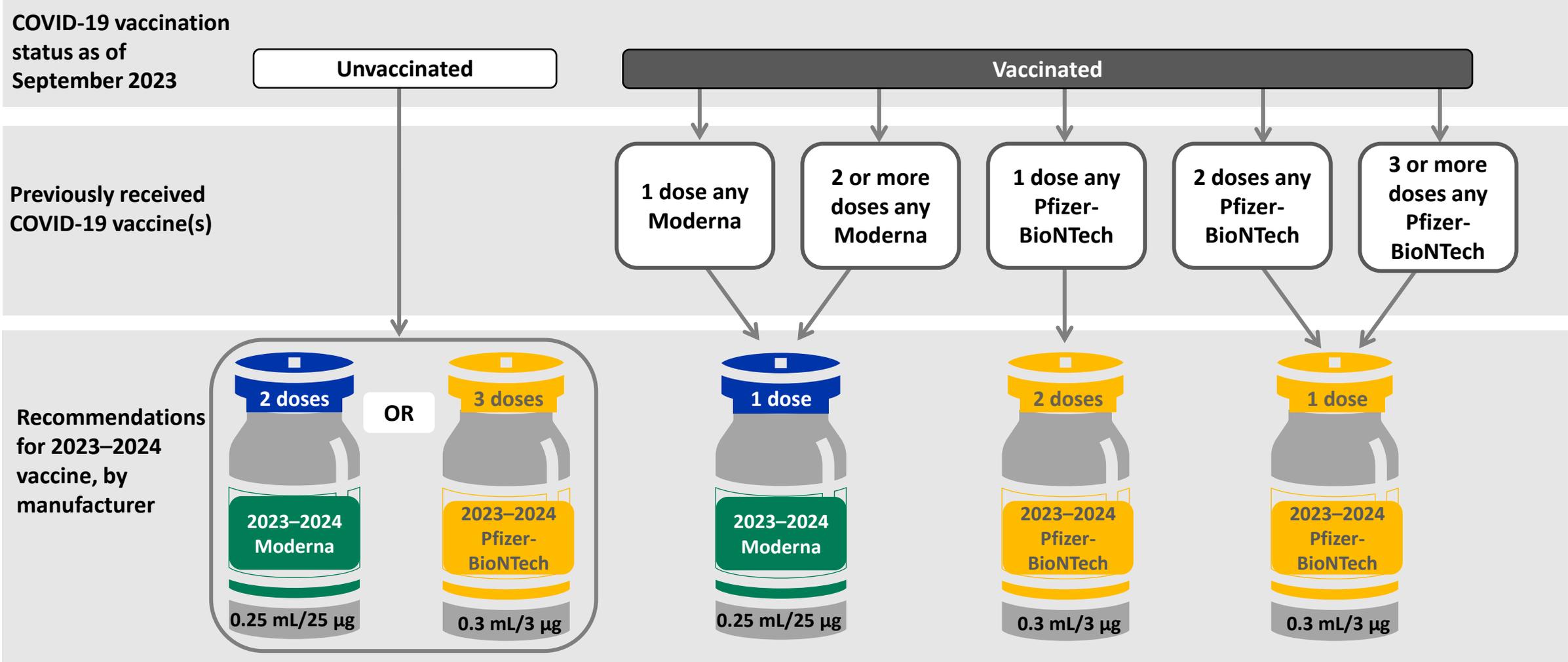
Proposed recommendations for children aged 6 months–4 years who are not moderately or severely immunocompromised

Proposed recommendations for children aged 6 months – 4 years without immunocompromise

Doses recommended:

- Initial series of 2 Moderna vaccine doses OR 3 Pfizer-BioNTech vaccine doses
 - **At least 1 dose of 2023–2024 COVID-19 vaccine**
-
- All doses should be homologous (i.e., from the same manufacturer)
 - All Moderna doses in ages 6 months – 11 years are now 25 µcg

Proposed recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 6 months–4 years*



*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Proposed recommendations for people aged 5 years and older who are not moderately or severely immunocompromised

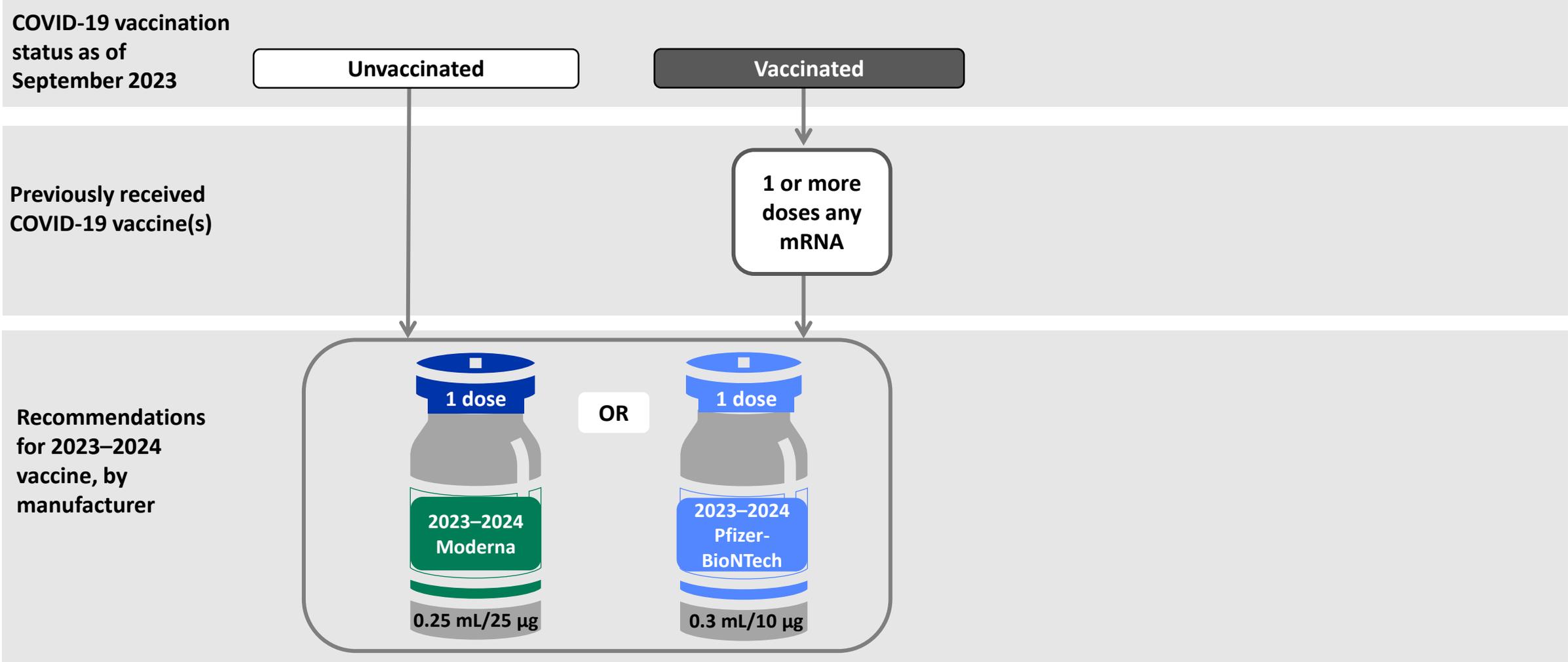
Proposed recommendations for people aged 5 years and older without immunocompromise

Doses recommended:

- **1 dose of 2023–2024 COVID-19 vaccine**, regardless of prior vaccination history

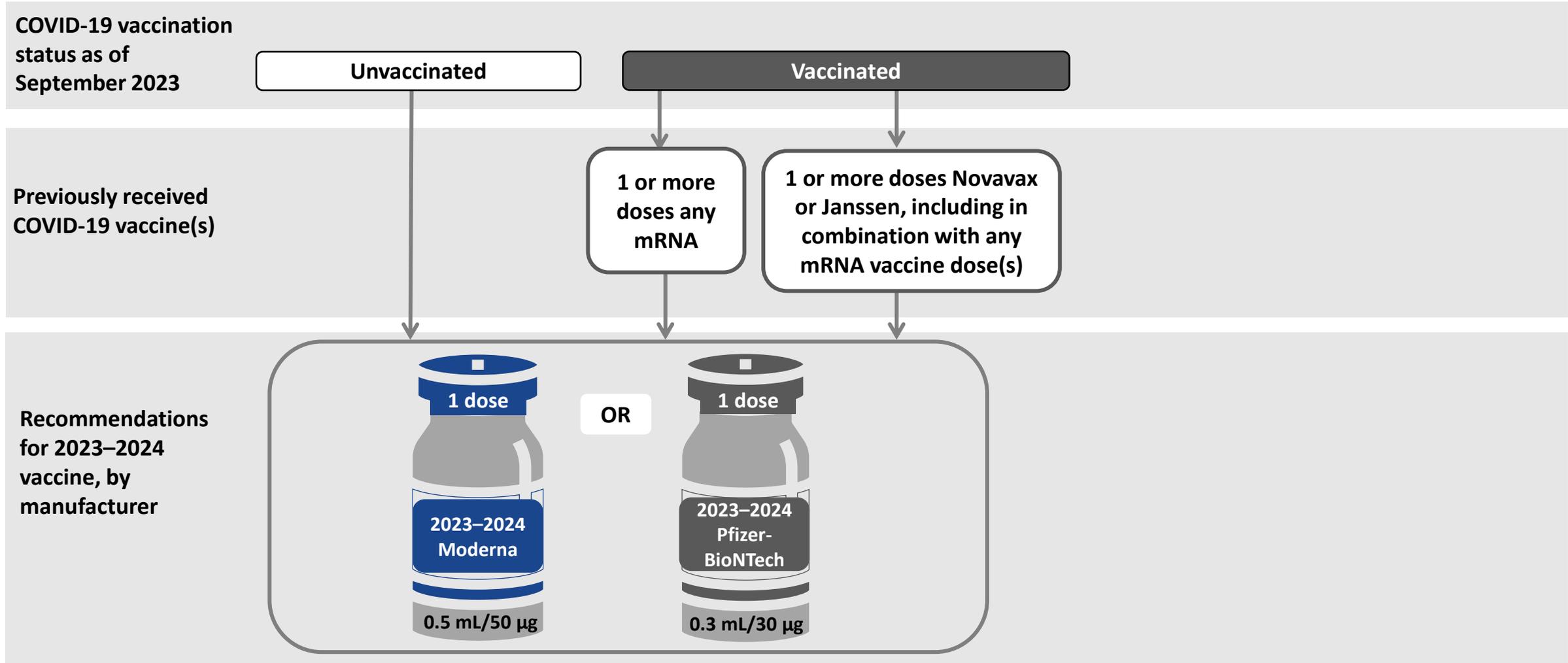
- New harmonized age cutoff for recommendations for young children for Moderna and Pfizer-BioNTech COVID-19 vaccines
- Resulting in simplified recommendations for 5-year-olds
- All Moderna doses in ages 6 months – 11 years are now 25 µcg
- 2023–2024 COVID-19 vaccine dose is recommended at least 2 months after receipt of the last COVID-19 vaccine dose

Proposed recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 5–11 years*

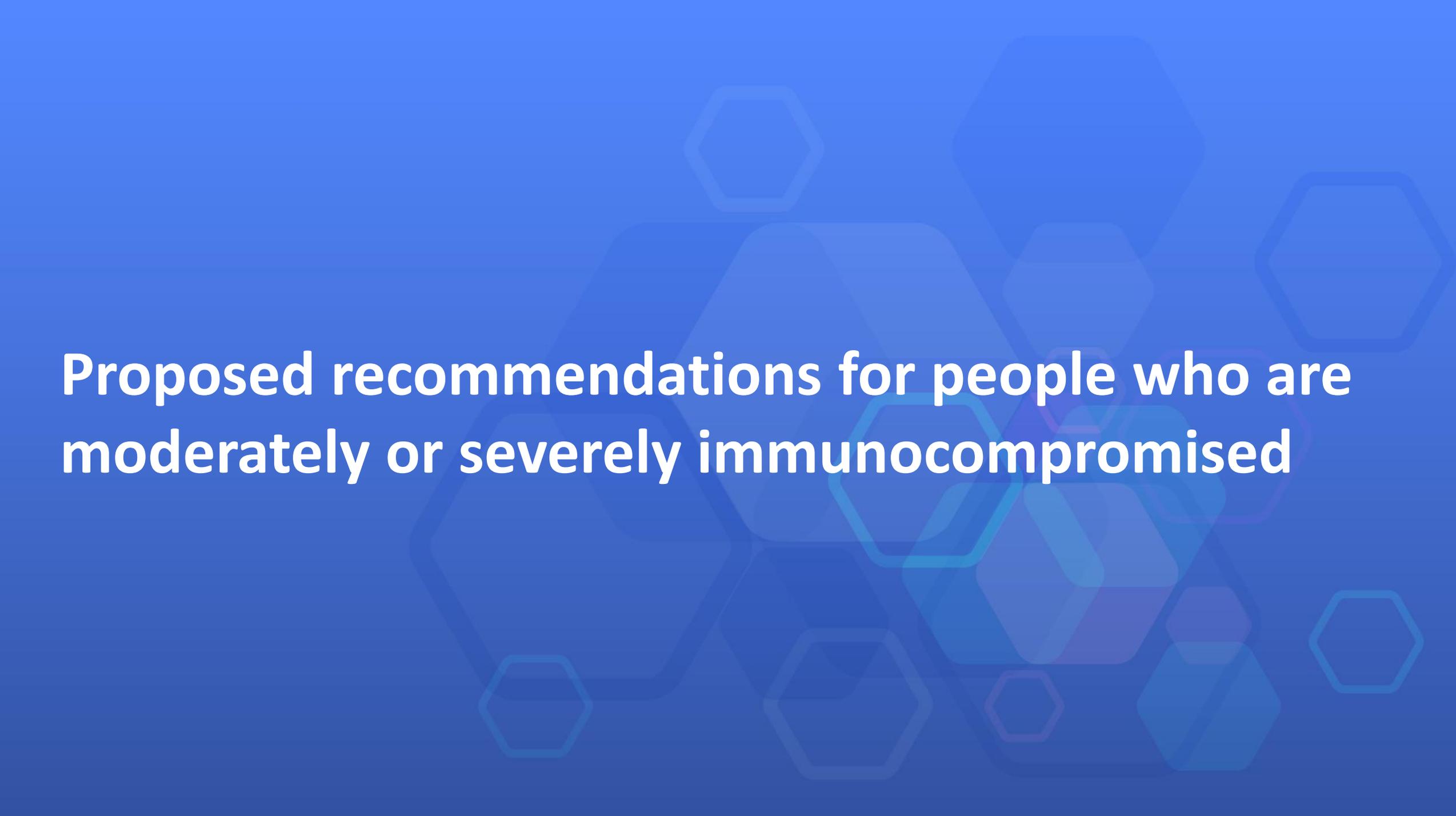


*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Proposed recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged ≥12 years*



*For information about administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

The background is a solid blue color with a pattern of overlapping hexagons. Some hexagons are solid blue, while others are outlined in a lighter blue. The hexagons vary in size and are scattered across the page.

Proposed recommendations for people who are moderately or severely immunocompromised

Proposed recommendations for people aged ≥ 6 months who are moderately or severely immunocompromised

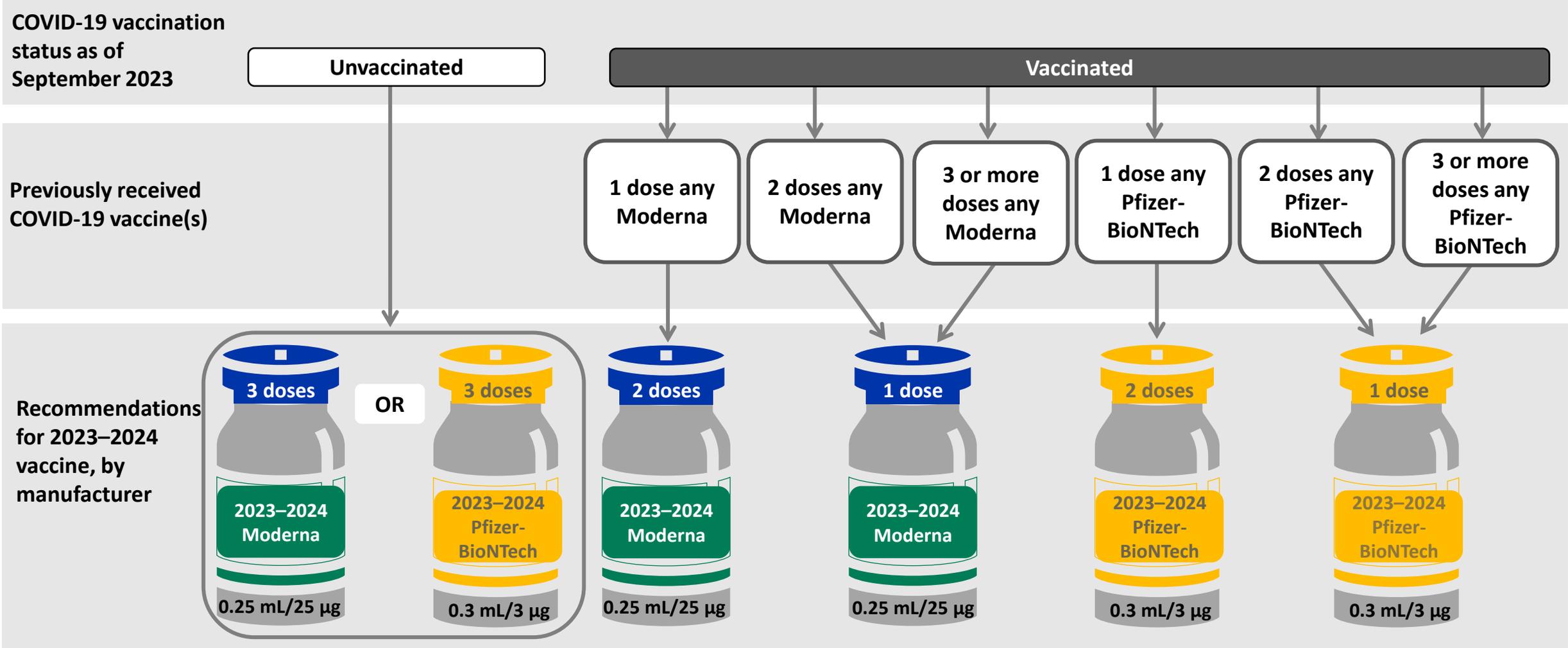
Doses recommended:

- Initial COVID-19 vaccine series*
- **At least 1 2023–2024 COVID-19 vaccine dose**
- May receive 1 or more additional 2023-2024 mRNA COVID-19 vaccine doses**

*Series of 3 homologous mRNA COVID-19 vaccine doses at time of initial vaccination. This could also include a history of receipt of 1 or more doses of Novavax or Janssen, including in combination with mRNA vaccine dose(s).

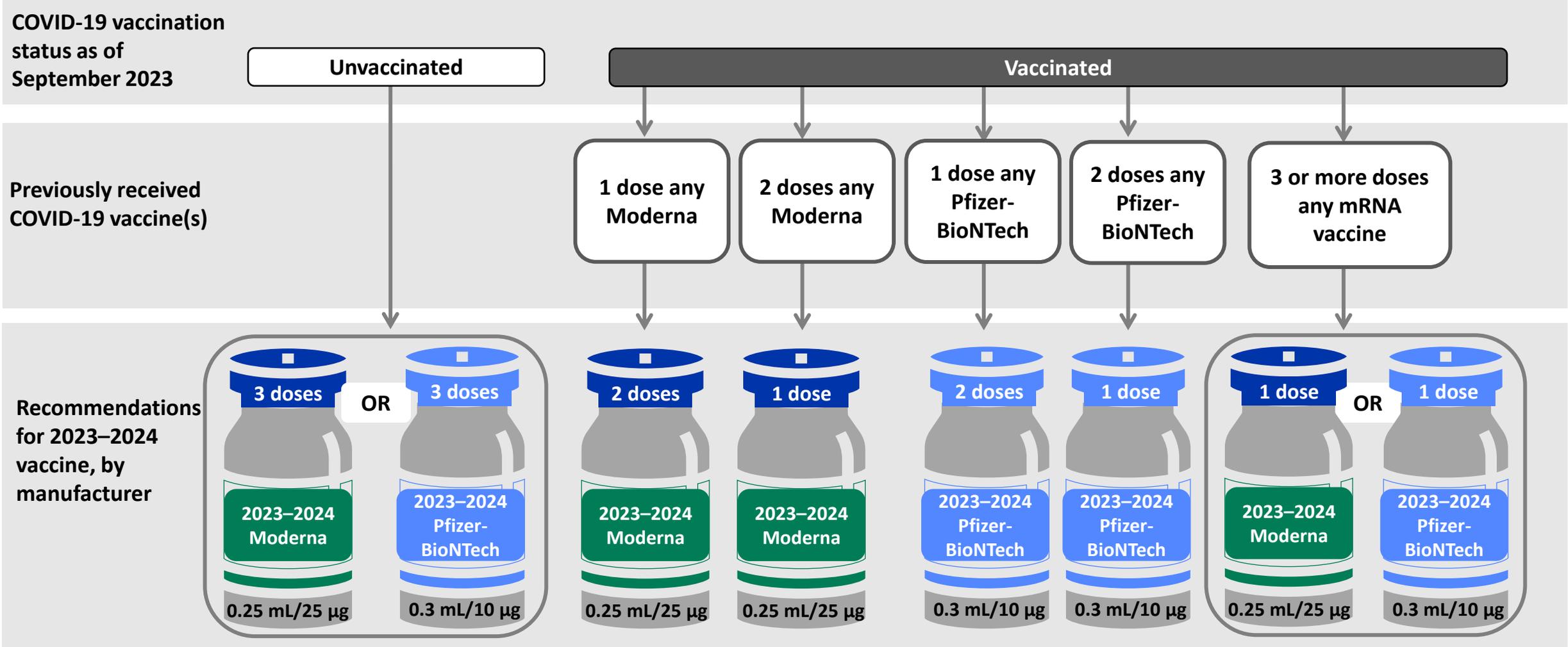
**Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.

Proposed recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 6 months–4 years*



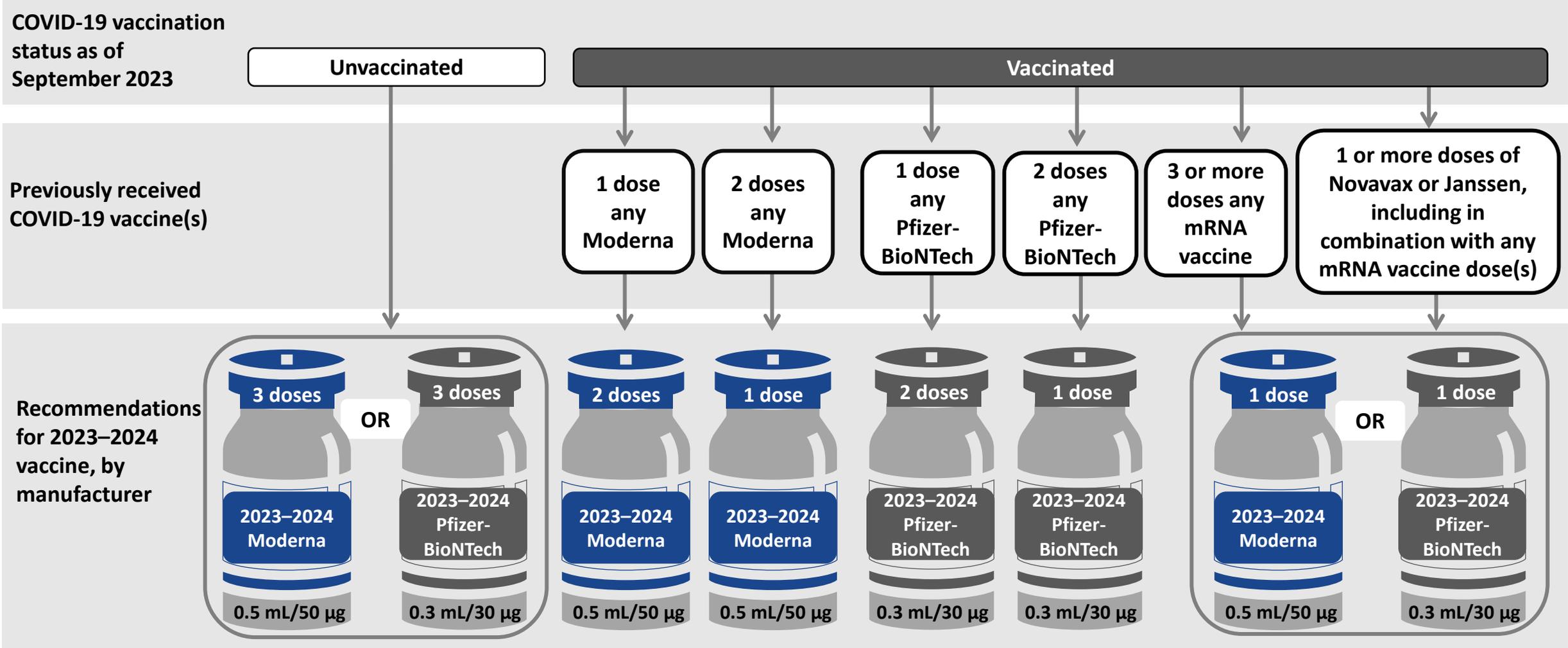
*For information about administration intervals, people who transition from age 4 years to age 5 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

Proposed recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 5–11 years*



*For information about administration intervals, people who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

Proposed recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged ≥12 years*

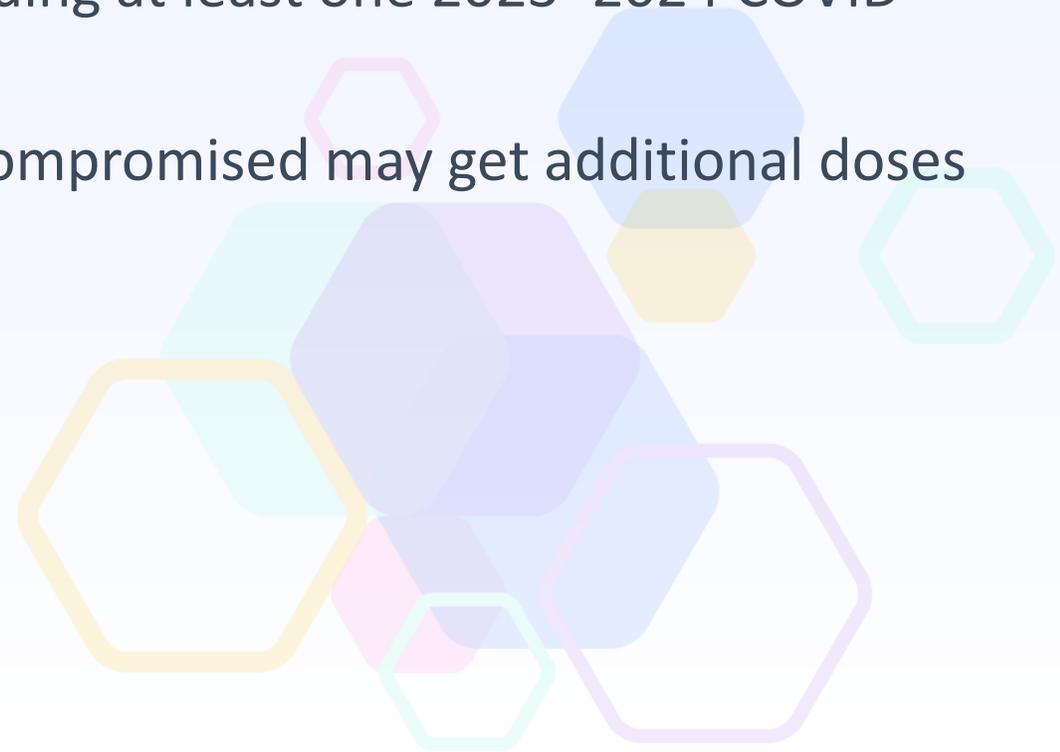


*For information about administration intervals, people who transition from age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

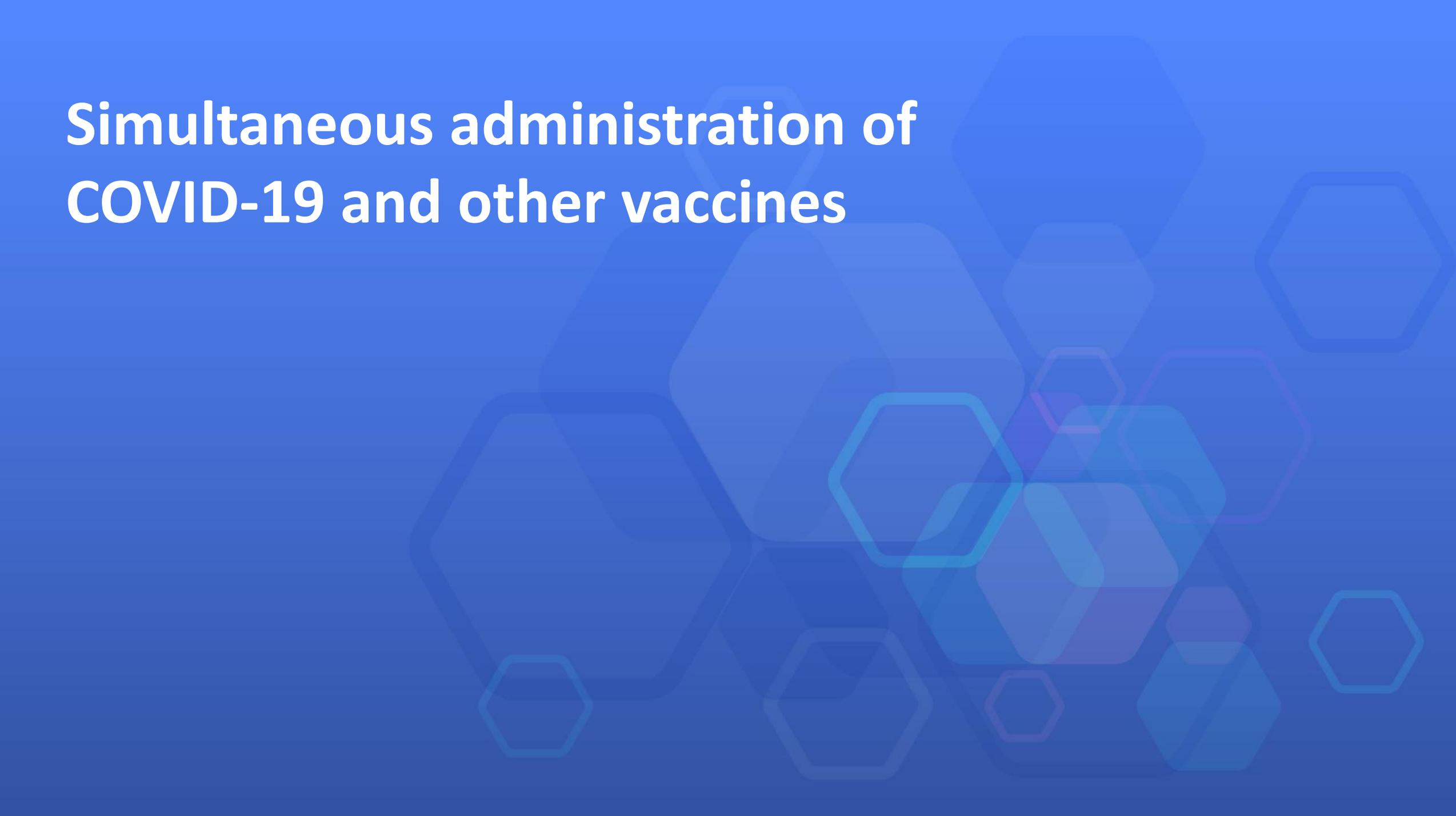
Proposed 2023 – 2024 COVID-19 Vaccine Up to Date

Definition

- Everyone aged 5 years and older are recommended get one 2023–2024 COVID-19 vaccine to be up to date.
- Children aged 6 months–4 years and people who are moderately or severely immunocompromised need multiple doses, including at least one 2023–2024 COVID-19 vaccine dose to be up to date.
- People who are moderately to severely immunocompromised may get additional doses of the 2023–2024 COVID-19 vaccine.



Simultaneous administration of COVID-19 and other vaccines



Simultaneous administration of COVID-19 and other vaccines

- In accordance with [General Best Practice Guidelines for Immunization](#), routine administration of all age-appropriate doses of vaccines simultaneously (i.e., administering more than one vaccine on the same clinic day or “coadministration”) is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.
 - Providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients; the [Health Alert Network \(HAN\)](#) published on September 5, 2023 may be consulted for additional information about simultaneous administration of these vaccines.
 - Simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody for certain infants and young children for prevention of RSV) is recommended
 - Coadministration of COVID-19 and RSV vaccine for older adults is acceptable
 - There are additional considerations if administering an orthopoxvirus vaccine and COVID-19 vaccine

[Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)

[Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR \(cdc.gov\)](#)

[Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over | CDC](#)

[Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Mpox Outbreak | Mpox | Poxvirus | CDC](#)