

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



Evidence to Recommendations Framework:

Additional Dose of 2023-2024 Formula COVID-19 Vaccine in Older Adults

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ACIP Meeting

February 28, 2024

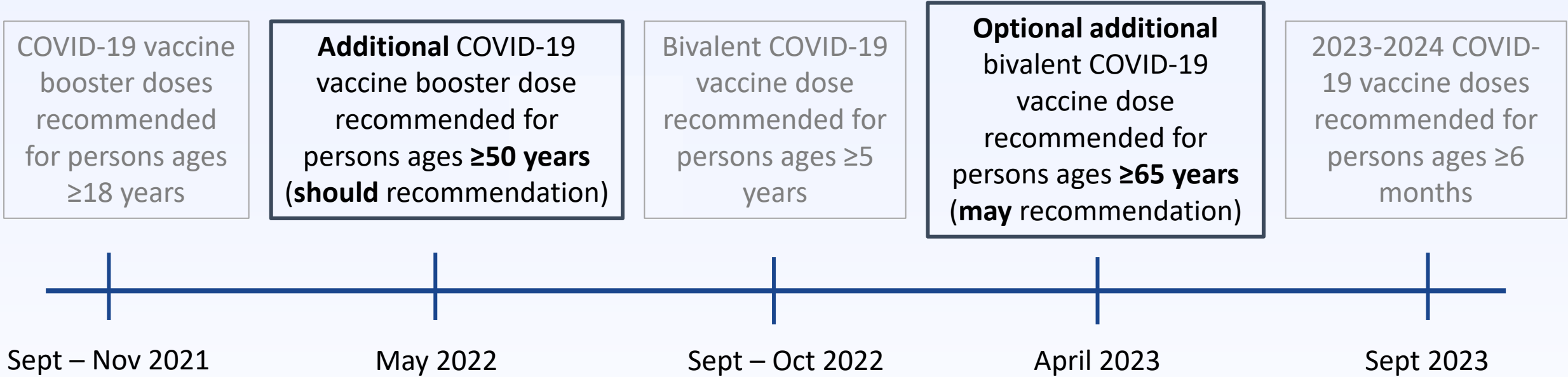
Evidence to Recommendations (EtR) Framework

Policy Question

- Should persons ages 65 years and older be recommended for an additional dose of 2023-2024 Formula COVID-19 vaccine?
 - Additional dose should be at least 4 months after previous updated (2023-2024) COVID-19 vaccine dose.
- Authorized and approved 2023-2024 Formula COVID-19 vaccines:
 - Moderna COVID-19 vaccine
 - Novavax COVID-19 vaccine
 - Pfizer-BioNTech COVID-19 vaccine



Timeline of additional dose recommendations



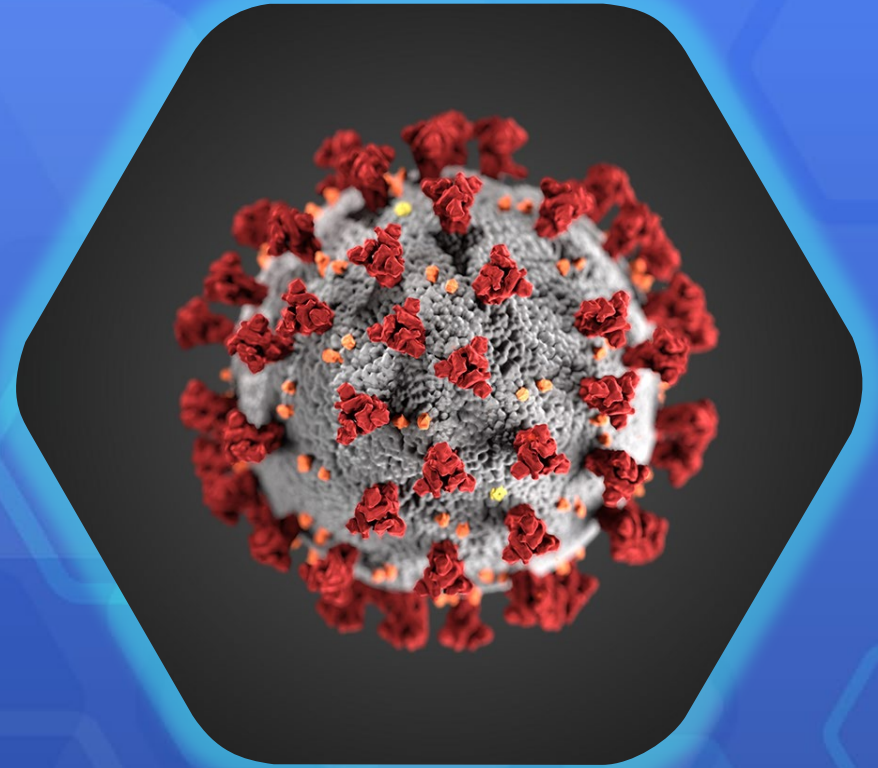
Current recommendations for additional doses of updated (2023-2024 Formula) COVID-19 vaccine

People who are moderately or severely immunocompromised:

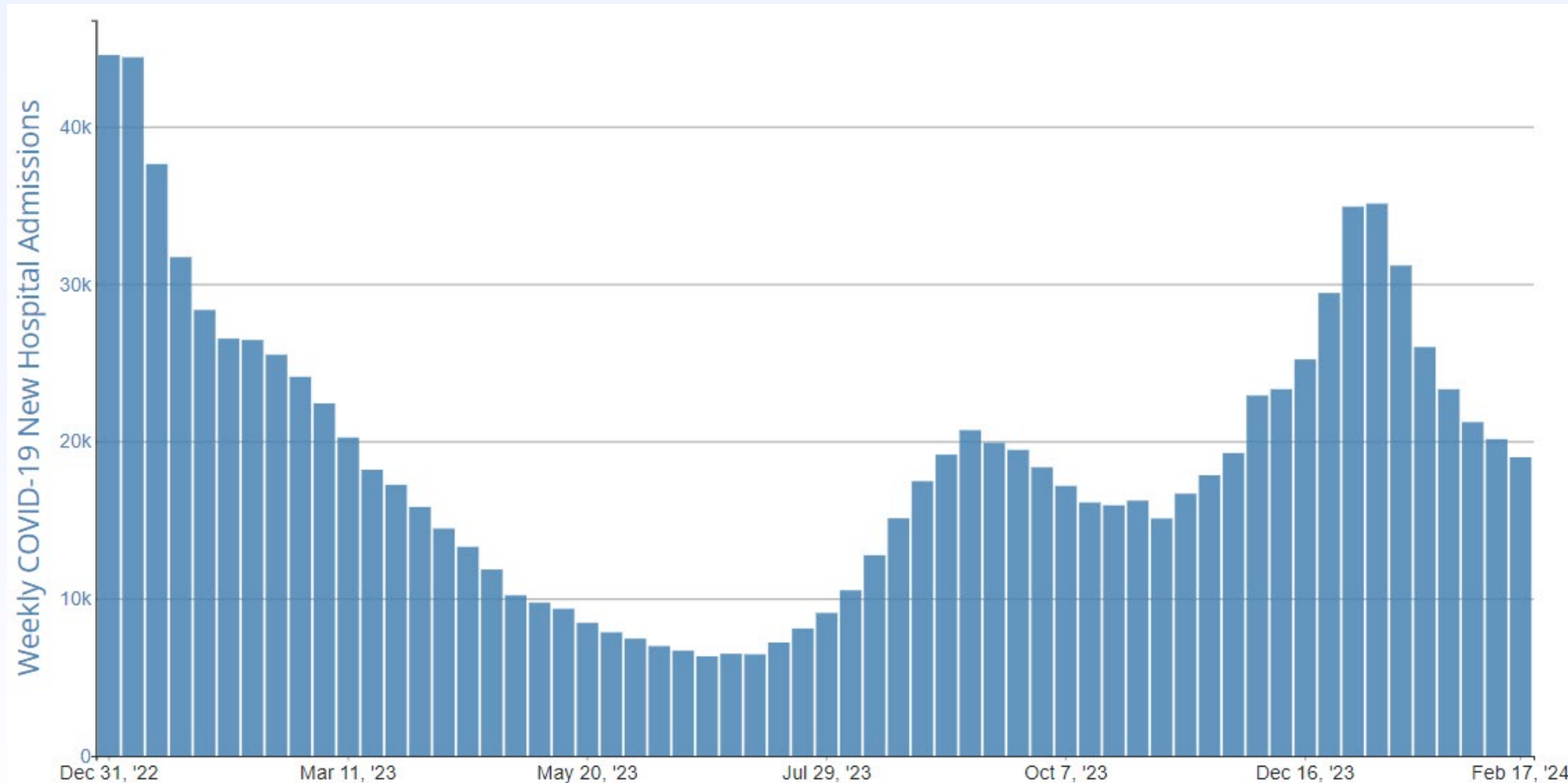
- Have the option to receive 1 additional dose of updated (2023-2024 Formula) COVID-19 Vaccine at least 2 months following the last recommended updated (2023-2024 Formula) COVID-19 vaccine dose.
- Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last updated (2023-2024 Formula) COVID-19 vaccine dose.

EtR Domain:

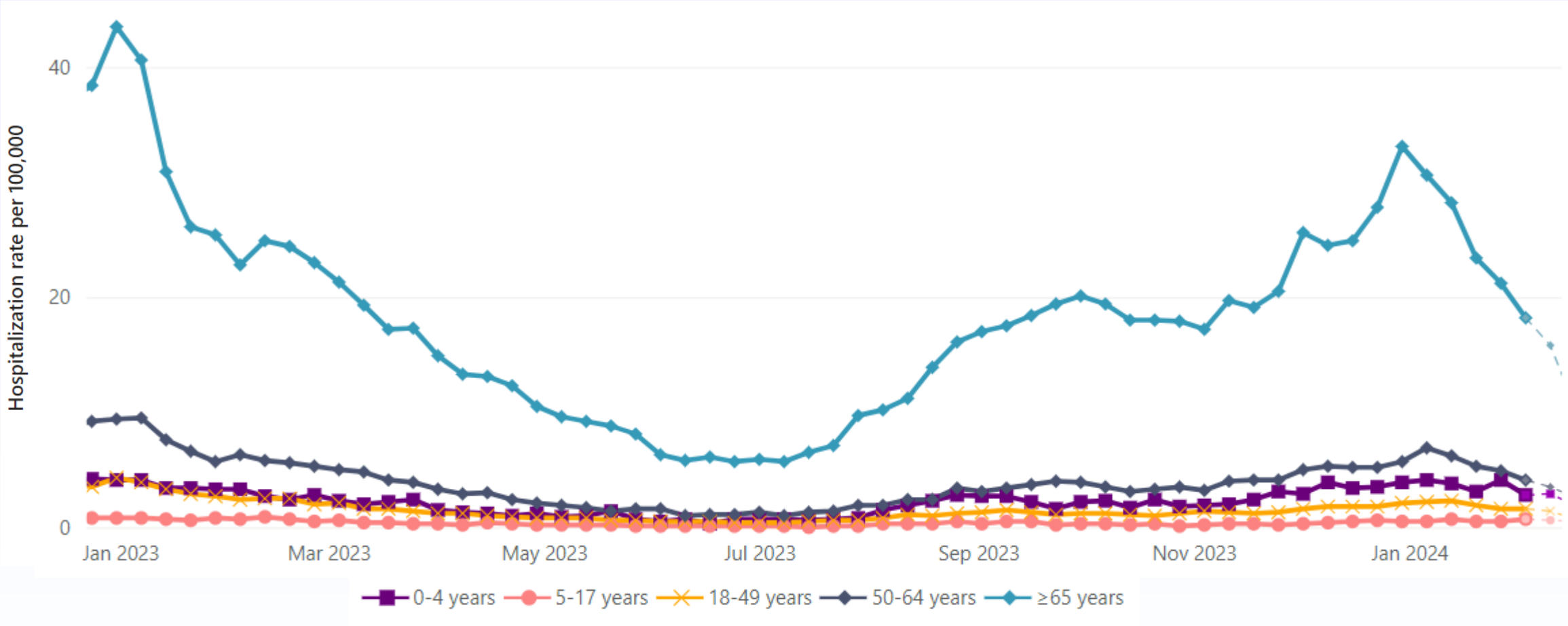
Public Health Problem



Weekly number of COVID-19 hospitalizations, United States, January 1, 2023 – February 17, 2024



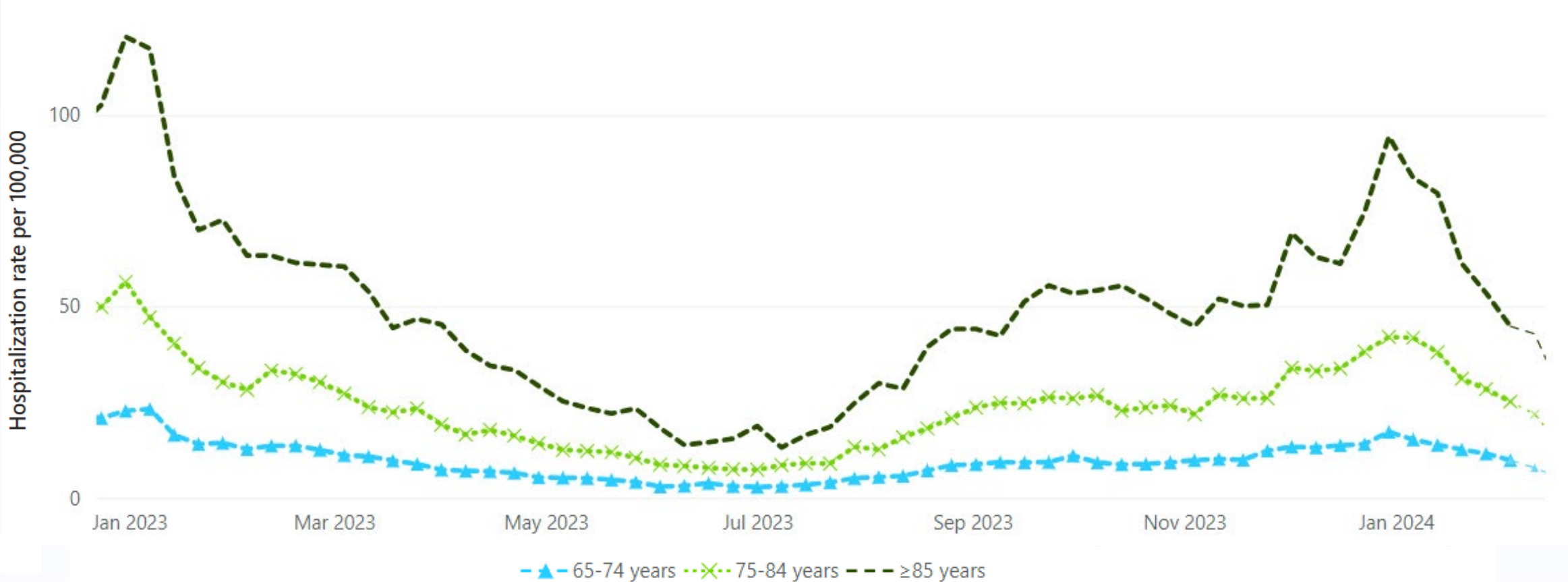
Weekly population-based rates of COVID-19-associated hospitalizations, by age group — COVID-NET, January 1, 2023 – February 24, 2024



Dashed lines indicate potential reporting delays and interpretation of trends should exclude these weeks.

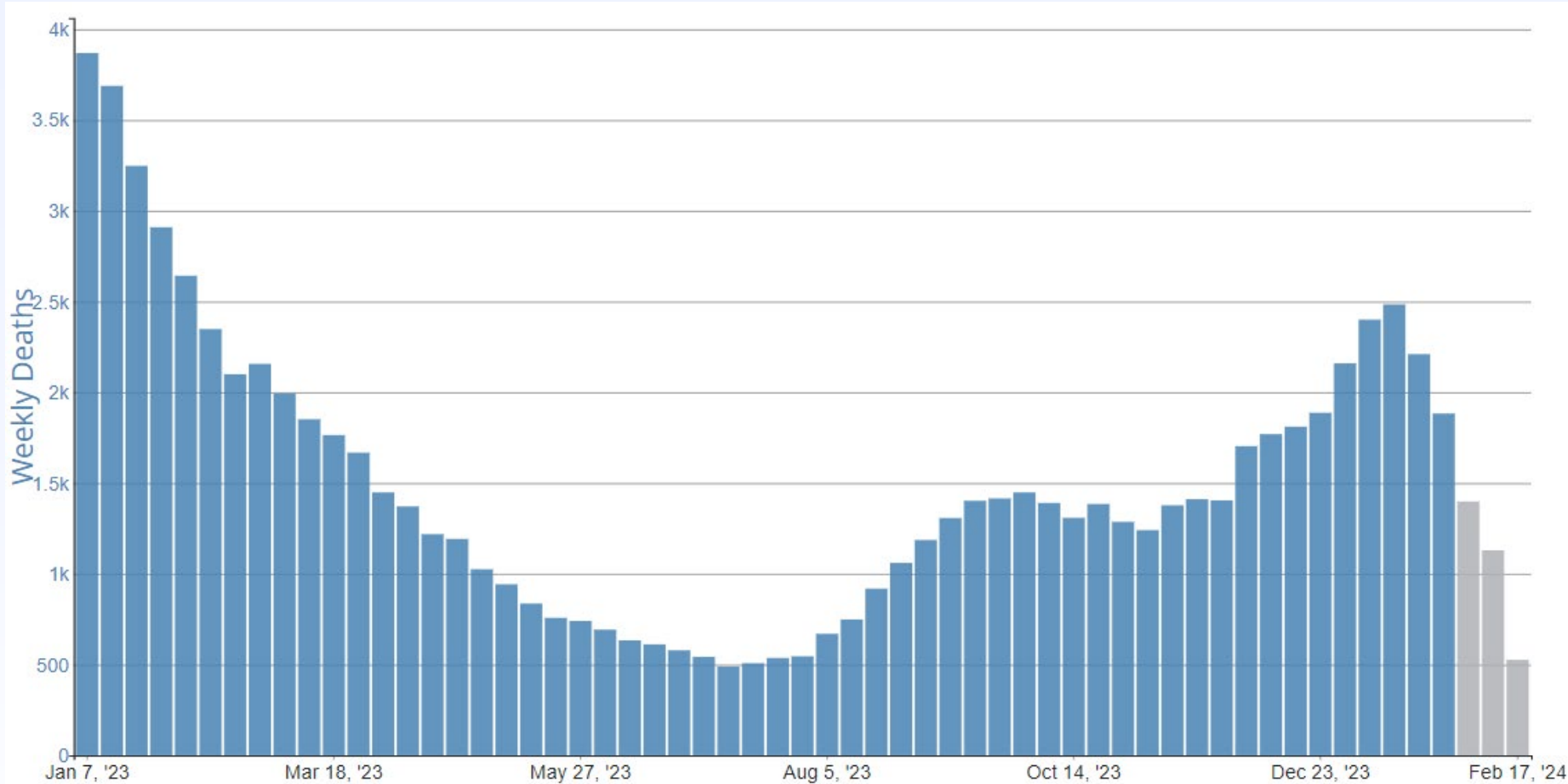
CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network>. Accessed February 23, 2024

Weekly population-based rates of COVID-19-associated hospitalization among adults ages ≥ 65 years, by age group—COVID-NET, January 1, 2023 – January 27, 2024



Thin dashed lines on the far right indicate potential reporting delays and interpretation of trends should exclude these weeks.
CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network>. Accessed February 6, 2024

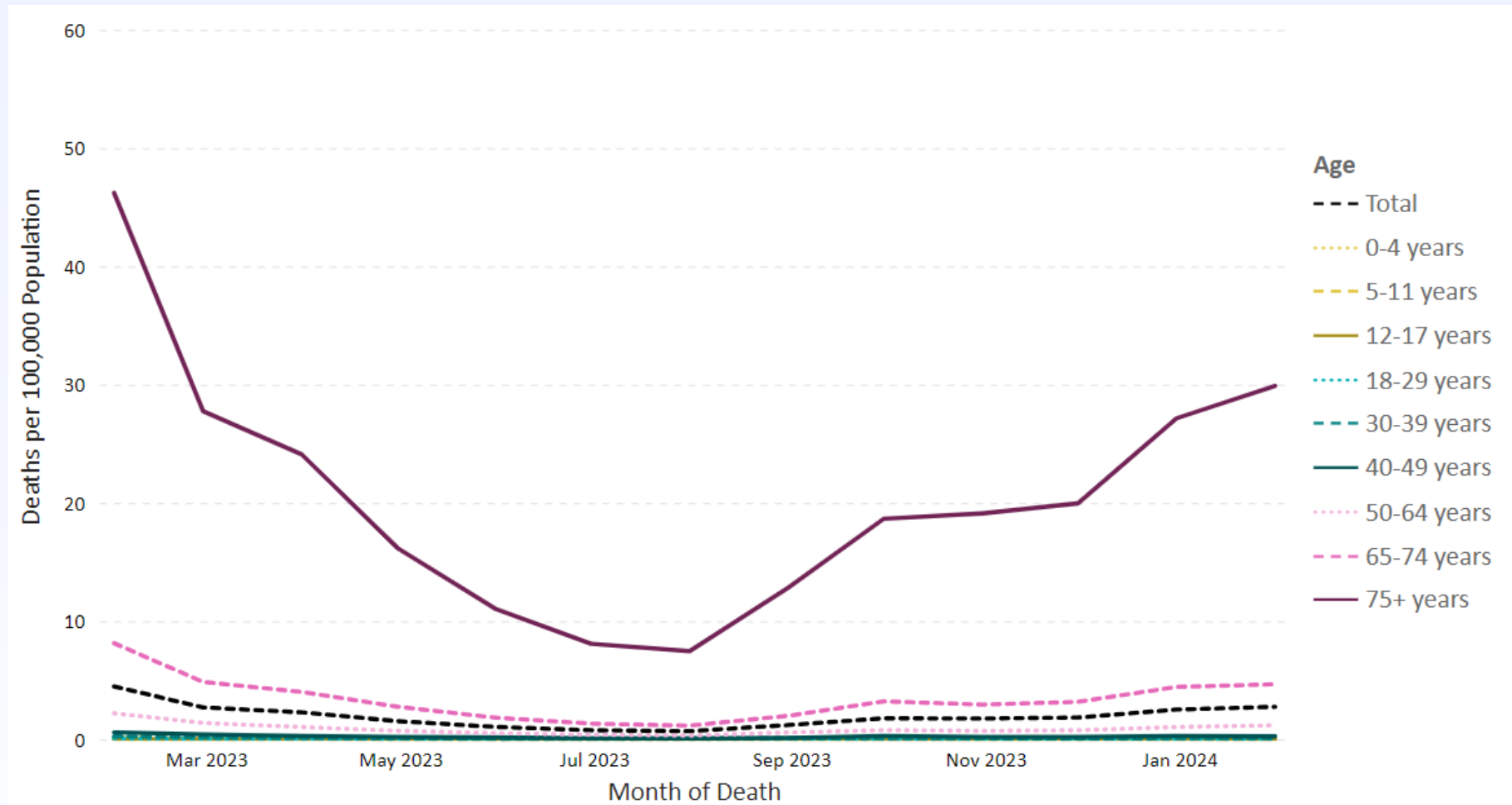
Weekly number of provisional COVID-19 deaths reported to CDC, United States, January 1, 2023 – February 17, 2024



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

Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD-10 code U07.1, on the death certificate. Death data are displayed by date of death (event).

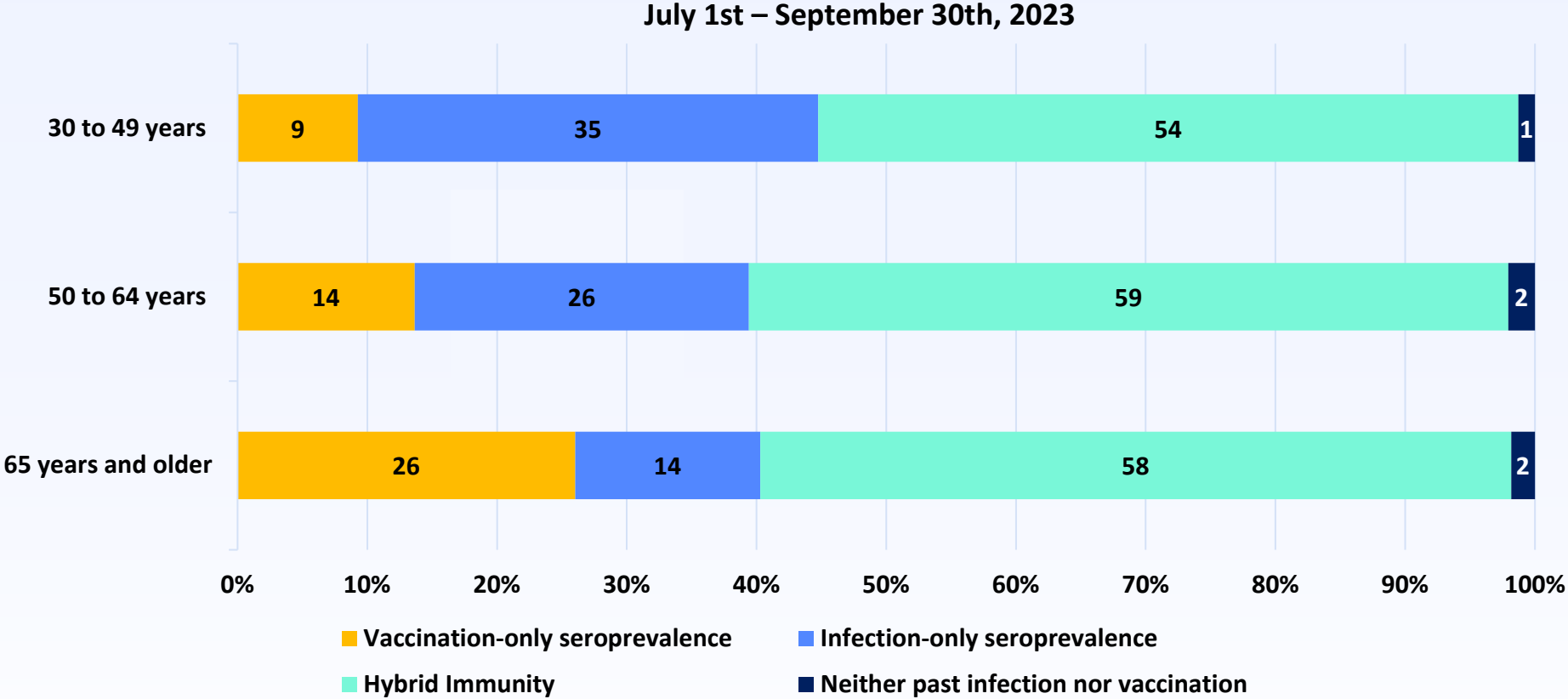
Monthly rates of provisional COVID-19 deaths by age group, United States, January 1, 2023 – January 31, 2024



Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD-10 code U07.1, on the death certificate. Death data are displayed by date of death (event).

Source: Provisional data from the CDC's National Center for Health Statistics (NCHS) National Vital Statistic System (NVSS); CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#demographicvertime>. Accessed February 23, 2024

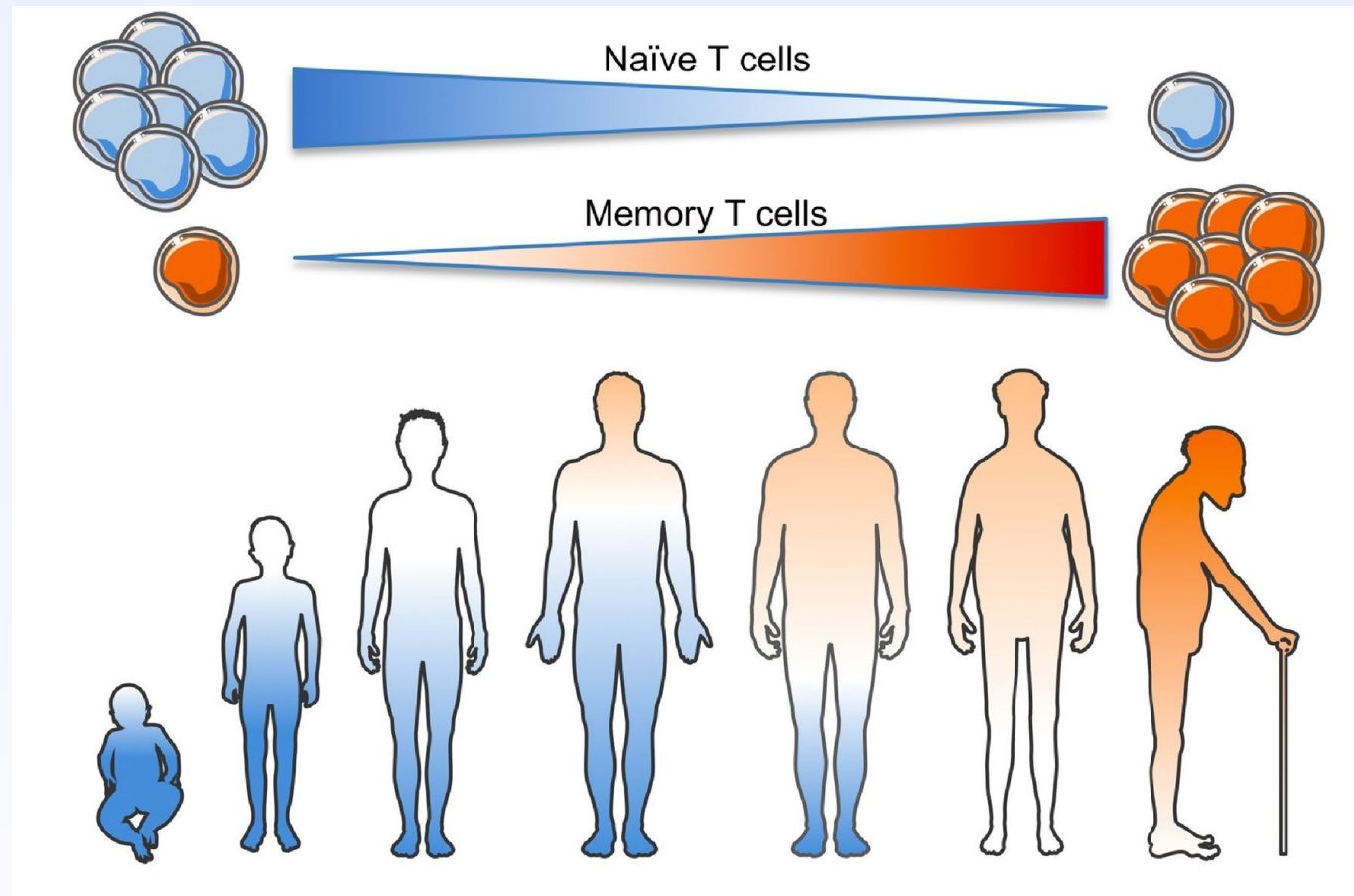
Weighted U.S. SARS-CoV-2 seroprevalence by vaccine and infection history and age, based on blood donations



Seroprevalence definition: The percentage of people with antibodies against a virus in their blood is known as seroprevalence.

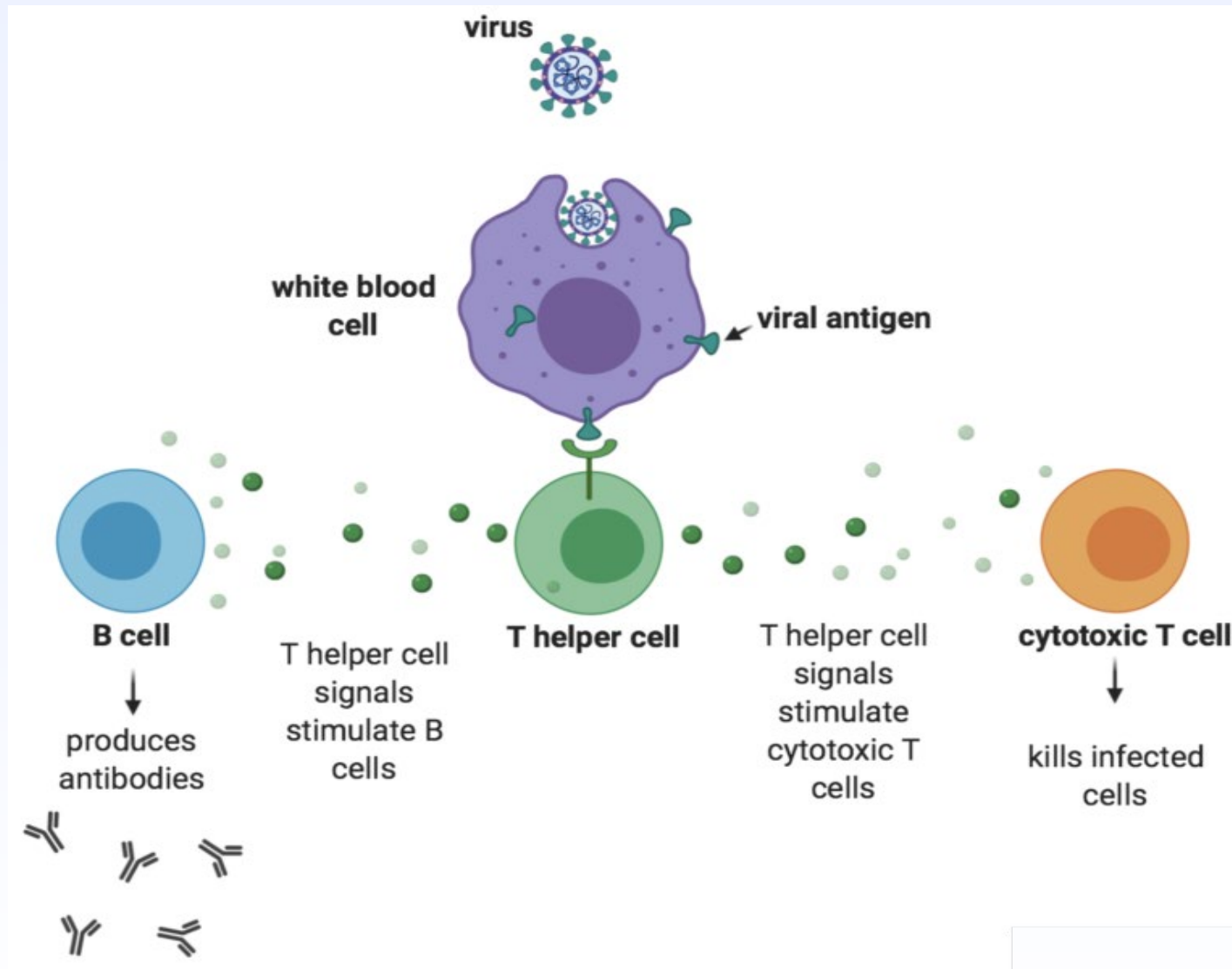
Methodology available at <https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022>

Pool of naïve T cells diminishes with age



Immunosenescence refers to age-associated immune decline that may result in an inefficient immune response to novel antigens and an inability to develop proper immunity against infections and upon vaccination.

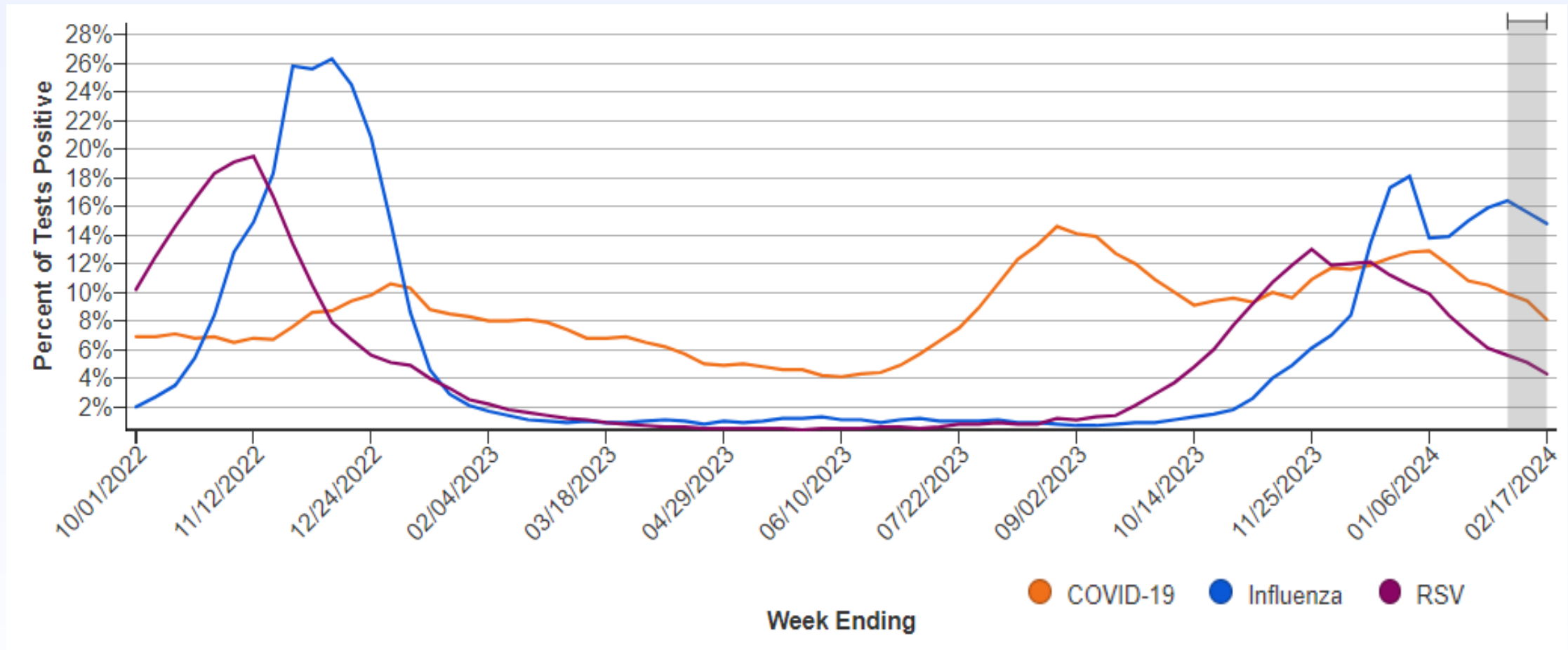
Adaptive immunity includes cellular and humoral responses



Insufficient pools of naïve T cells impacts ability to generate:

- Neutralizing antibody responses
- Cytotoxic T cells

Weekly percent of tests positive for COVID-19, Influenza, and RSV, United States, October 1, 2022 – February 17, 2024

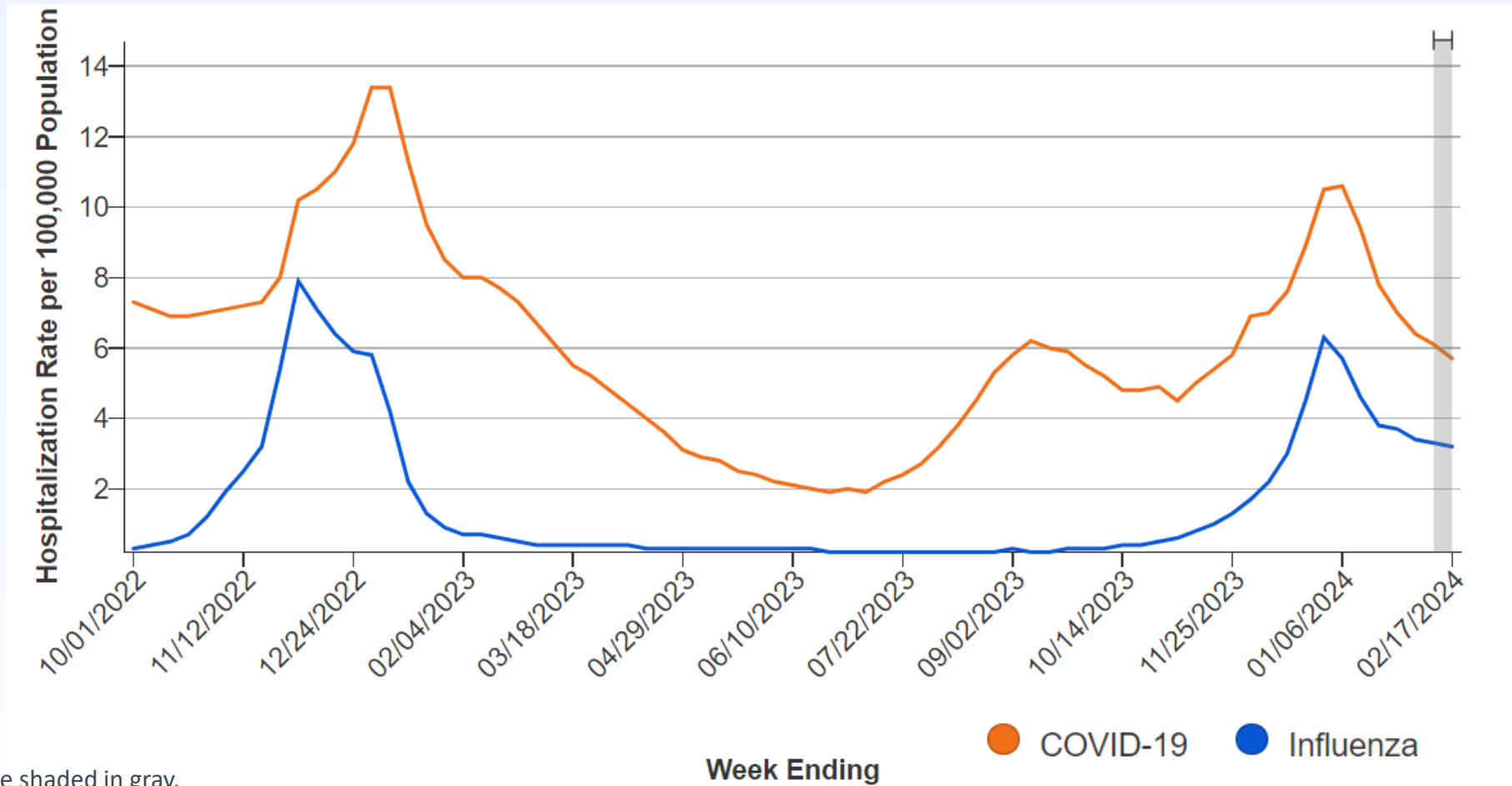


Preliminary data are shaded in gray.

Sources: COVID-19 and RSV: National Respiratory and Enteric Virus Surveillance System (NREVSS), a sentinel network of laboratories located through the US, includes clinical, public health and commercial laboratories; additional information available at: <https://www.cdc.gov/surveillance/nrevss/index.html>. Influenza: Clinical laboratory test results from NREVSS and U.S. World Health Organization collaborating laboratories; more details about influenza virologic surveillance are available here: <https://www.cdc.gov/flu/weekly/overview.htm>.

CDC Respiratory Virus Activity Levels. <https://www.cdc.gov/respiratory-viruses/data-research/dashboard/activity-levels.html>. Accessed February 6, 2024

Weekly hospitalization rate per 100,000 population, United States, October 1, 2022 – February 17, 2024



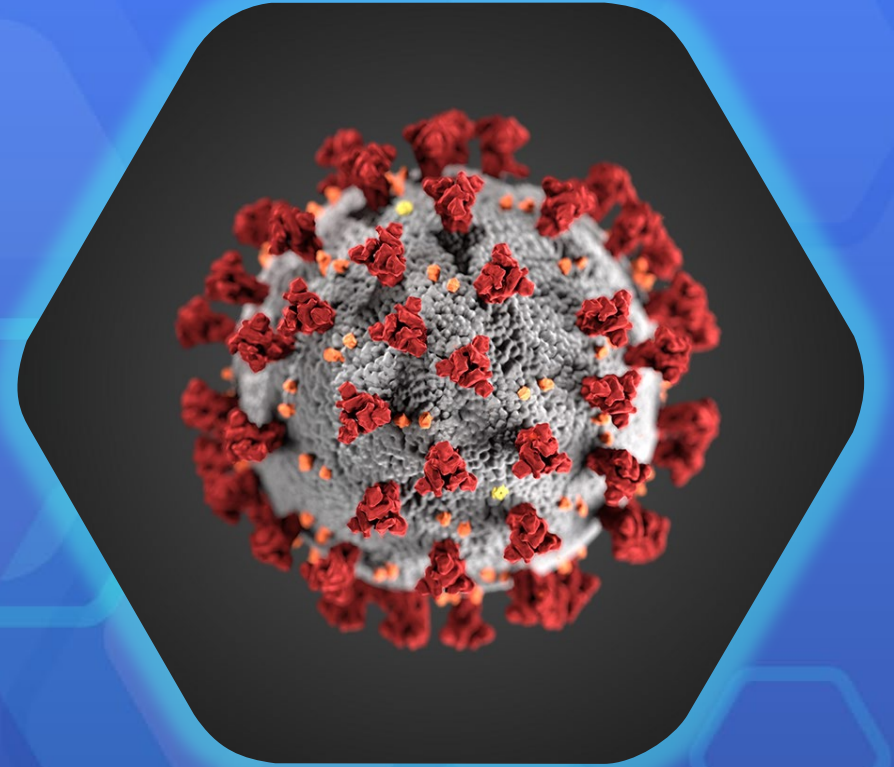
Preliminary data are shaded in gray.

Dashed line represents the nadir for COVID-19 hospitalization rates.

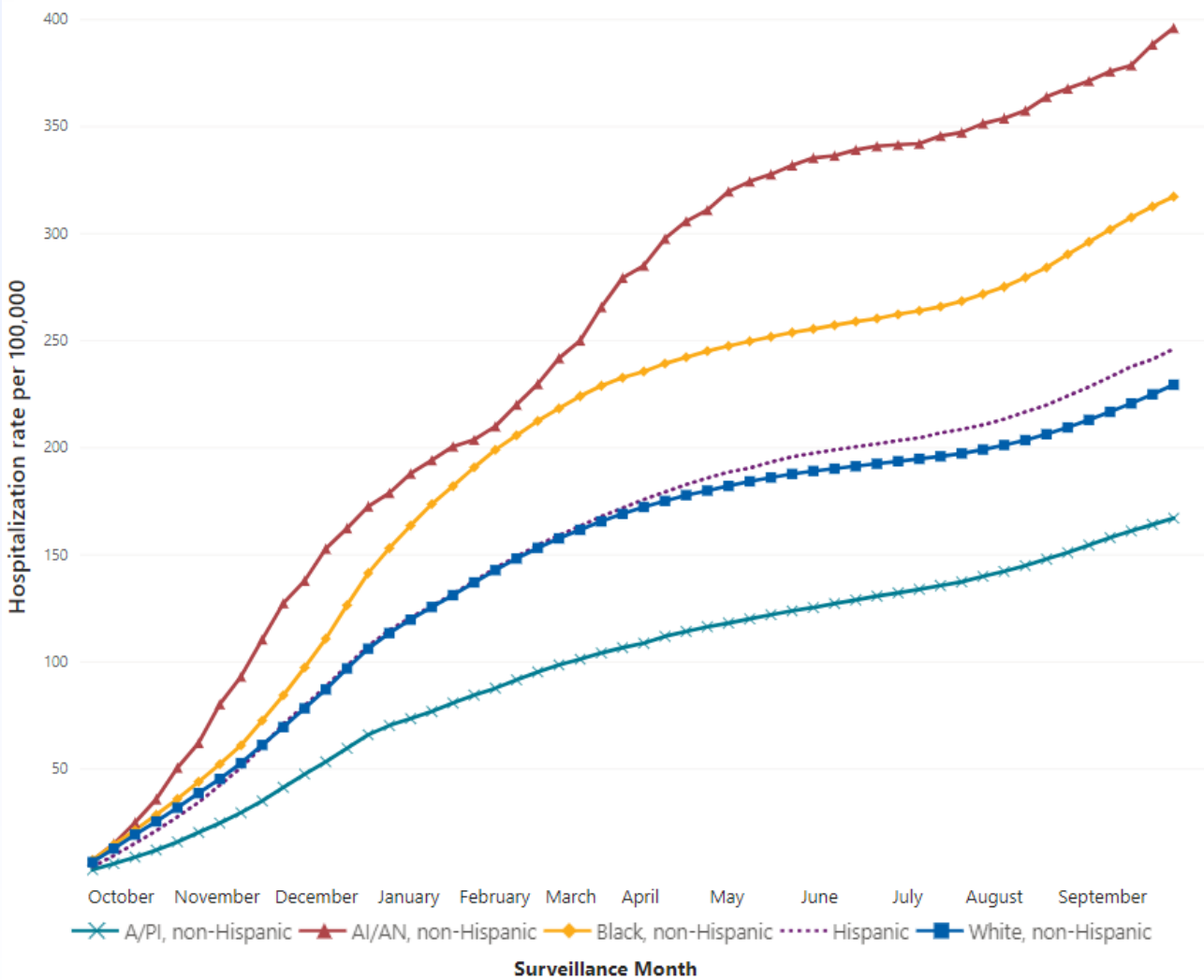
CDC Respiratory Virus Activity Levels. National Healthcare Safety Network. <https://www.cdc.gov/respiratory-viruses/data-research/dashboard/illness-severity.html>. Accessed February 23, 2024

Domain Equity Question:

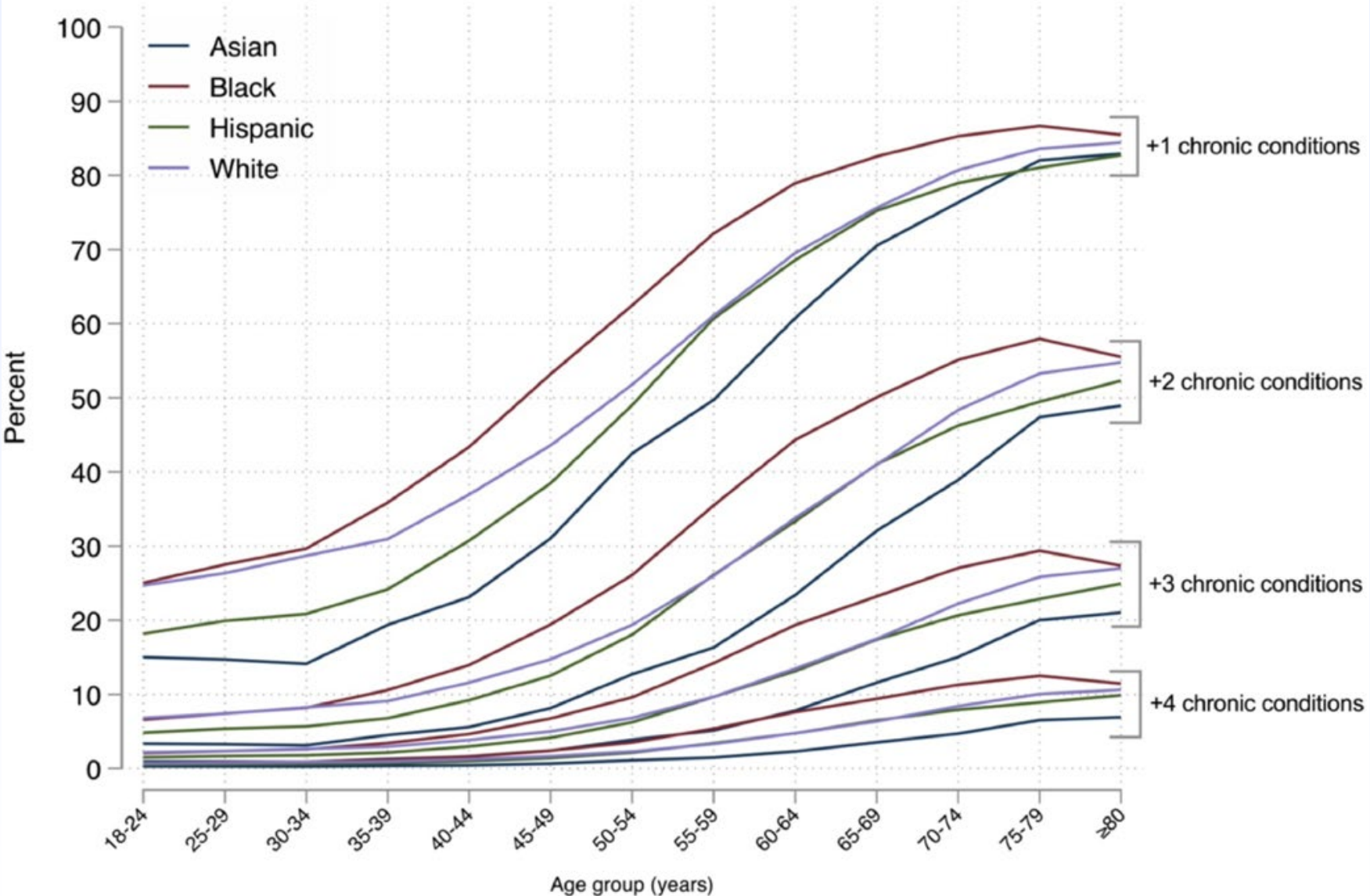
Does the problem impact all populations equally?



Age-adjusted cumulative COVID-19 hospitalizations per 100,000 population by race and ethnicity — COVID-NET, October 2022 – September 2023



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 hospitalizations peaked in late December/early January, however there are still approximately 20,000 new hospital admissions and 2,000 deaths due to COVID-19 each week.
- Persons ages ≥ 65 years have the highest COVID-19 hospitalization rates.
 - Hospitalization rates within this age group increase with increasing age.
- Persons ages ≥ 75 years have the highest COVID-19 mortality rates.
- Immunosenescence and higher prevalence of vaccine-only immunity in older adults compared to younger adults suggest that more frequent doses may be needed to maintain protection in this population.
- While there are increases in COVID-19 during respiratory virus season, COVID-19 hospitalizations and deaths continue throughout the year due to ongoing circulation of SARS-CoV-2.
- Inequities in COVID-19 hospitalizations by race and ethnicity continue and should be considered in the context of an age-based recommendation.

Public Health Problem

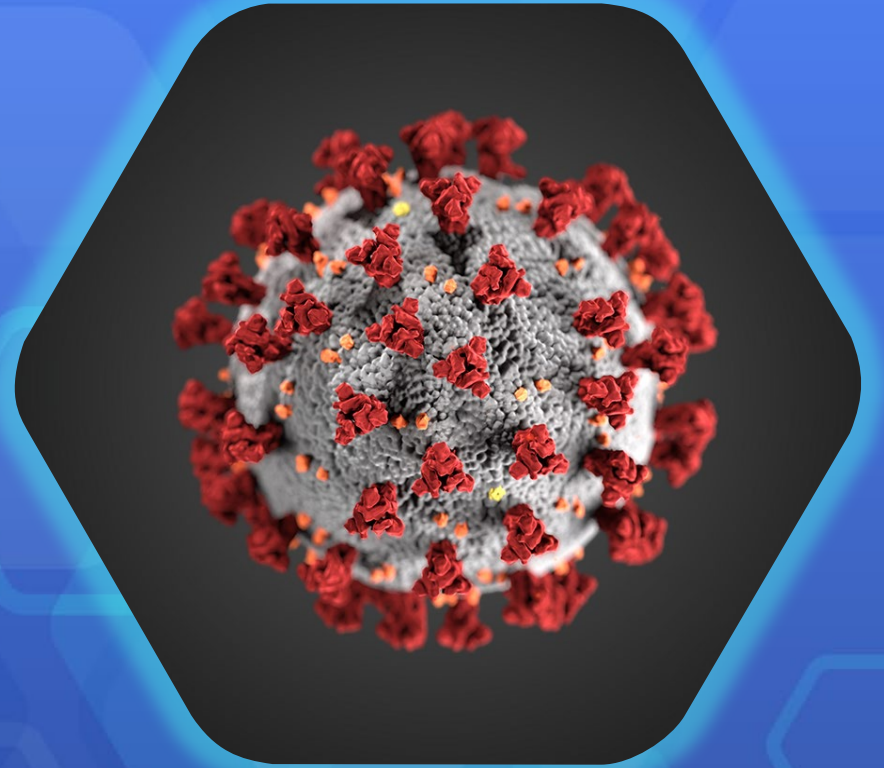
Work Group Interpretation

Is COVID-19 disease among persons ages 65 years and older of public health importance?

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

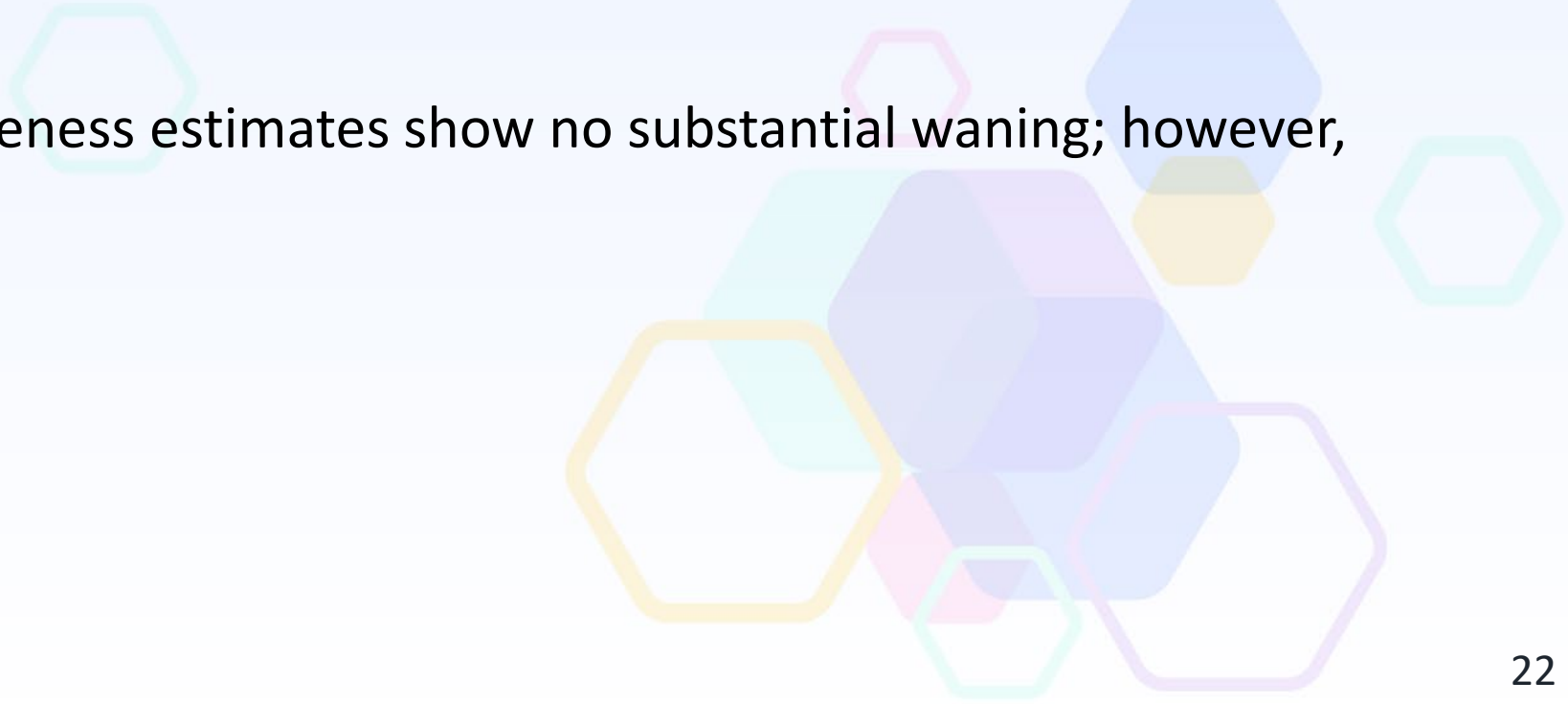
EtR Domain:

Benefits and Harms



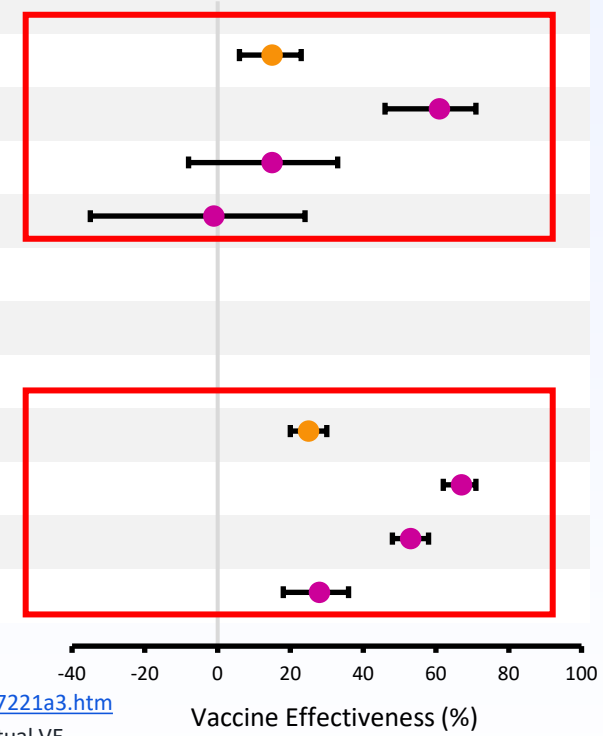
2023-2024 Formula COVID-19 vaccine effectiveness

- Updated (2023-2024) COVID-19 vaccination provided increased protection against symptomatic SARS-CoV-2 infection and COVID-19-associated ED/UC visits and hospitalizations compared to no updated vaccine dose.
- Receipt of updated (2023-2024) COVID-19 vaccine provides protection against JN.1 and other circulating variants.
- These early vaccine effectiveness estimates show no substantial waning; however, waning is expected.



VISION: Absolute VE of *original monovalent* and *bivalent* booster doses against *hospitalization* among immunocompetent adults, by age group – September 2022 – August 2023

mRNA Dosage Pattern	Total tests	SARS-CoV-2-test-positive, N (%)	Median interval since last dose, days (IQR)	Adjusted VE (95% CI)
18-64 years				
Unvaccinated (ref)	13,089	803 (6)	--	Ref
Original monovalent doses only	19,799	1,129 (6)	455 (333-575)	15 (6 to 23)
Bivalent booster, 7-59 days earlier	1,208	45 (4)	33 (21-45)	61 (46 to 71)
Bivalent booster, 60-119 days earlier	1,248	87 (7)	87 (73-102)	15 (-8 to 33)
Bivalent booster, 120-179 days earlier	1,075	59 (6)	147 (134-163)	-1 (-35 to 24)*
≥65 years				
Unvaccinated (ref)	12,015	1,688 (14)	--	Ref
Original monovalent doses only	37,001	4,216 (11)	402 (288-555)	25 (20-30)
Bivalent booster, 7-59 days earlier	4,607	328 (7)	35 (21-48)	67 (62-71)
Bivalent booster, 60-119 days earlier	5,252	490 (9)	88 (73-104)	53 (48-58)
Bivalent booster, 120-179 days earlier	4,482	415 (9)	149 (134-164)	28 (18-36)

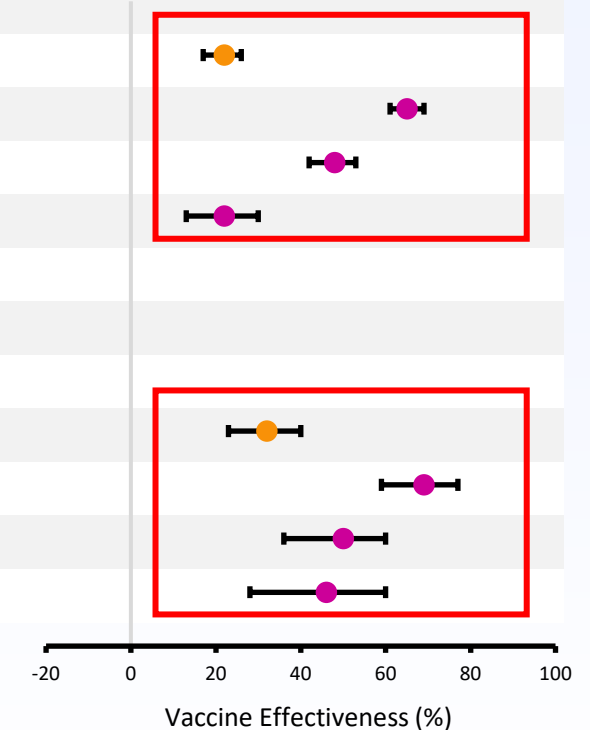


VE estimates adjusted for age, sex, race and ethnicity, geographic region, and calendar time. Updated from: Link-Gelles et al., MMWR, <https://www.cdc.gov/mmwr/volumes/72/wr/mm7221a3.htm>

* These estimates are imprecise, which might be due to there being a relatively small number of persons in each level of vaccination or case status. This imprecision indicates that the actual VE could be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual could increase precision and allow more precise interpretation.

VISION: Absolute VE of *original monovalent* and *bivalent* booster doses against *hospitalization* and *critical illness* among immunocompetent adults aged ≥18 years – September 2022 – August 2023

mRNA Dosage Pattern	Total tests	SARS-CoV-2-test-positive, N (%)	Median interval since last dose, days (IQR)	Adjusted VE (95% CI)
Hospitalization				
Unvaccinated (ref)	25,104	2,491 (10)	--	Ref
Original monovalent doses only	56,800	5,345 (9)	420 (306-563)	22 (17-26)
Bivalent booster, 7-59 days earlier	5,815	373 (6)	34 (21-47)	65 (61-69)
Bivalent booster, 60-119 days earlier	6,500	577 (9)	87 (73-103)	48 (42-53)
Bivalent booster, 120-179 days earlier	5,557	474 (9)	149 (134-164)	22 (13-30)
Critical illness				
Unvaccinated (ref)	23,140	527 (2)	--	Ref
Original monovalent doses only	52,352	897 (2)	422 (306-564)	32 (23-40)
Bivalent booster, 7-59 days earlier	5,504	62 (1)	34 (21-47)	69 (59-77)
Bivalent booster, 60-119 days earlier	6,023	100 (2)	87 (73-103)	50 (36-60)
Bivalent booster, 120-179 days earlier	5,144	61 (1)	149 (134-164)	46 (28-60)



Critical illness defined as admission to intensive care unit or death; case-patients were persons admitted to ICU or who experienced death associated with COVID-19, and control patients were persons hospitalized without COVID-19. VE estimates adjusted for age, sex, race and ethnicity, geographic region, and calendar time. Updated from: Link-Gelles et al., MMWR, <https://www.cdc.gov/mmwr/volumes/72/wr/mm7221a3.htm>

Effectiveness of an additional dose of COVID-19 vaccine

- No clinical trial immunogenicity data of an additional dose of 2023-2024 COVID-19 vaccine.
- Initial dose of 2023-2024 COVID-19 vaccine elicits robust neutralizing antibodies and provides protection against JN.1 and other circulating variants.^{1,2}
- Effectiveness of an additional dose in older adults has been demonstrated by past additional doses
 - Among adults aged ≥ 50 years eligible to receive a second original monovalent mRNA COVID-19 vaccine booster dose, VE for COVID-19–associated ED/UC encounters during the BA.2/BA.2.12.1 period was 32% at ≥ 120 days after the third dose but increased to 66% ≥ 7 days after the fourth dose. VE against COVID-19–associated hospitalization was 55% ≥ 120 days after the third dose but increased to 80% ≥ 7 days after the fourth dose.³
 - In a large cohort of nursing home residents, receipt of a second original monovalent mRNA COVID-19 booster dose during circulation of SARS-CoV-2 Omicron subvariants was 74% effective at 60 days against severe COVID-19–related outcomes (including hospitalization or death) and 90% against death alone compared with receipt of a single booster dose.⁴

1. <https://www.biorxiv.org/content/10.1101/2023.11.26.568730v2>

2. <https://www.cdc.gov/mmwr/volumes/73/wr/mm7304a2.htm>

3. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm>

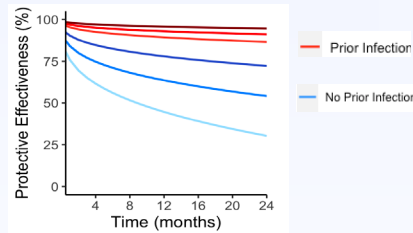
4. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7139a2.htm>

Microsimulation modeling study compares frequency of COVID-19 vaccine by risk group



Step 1: Assign to risk group

- Age group: 18-49, 50-64, 65-74, 75+ years
- Immune status: immunocompetent, immunocompromised (mild, moderate/severe)



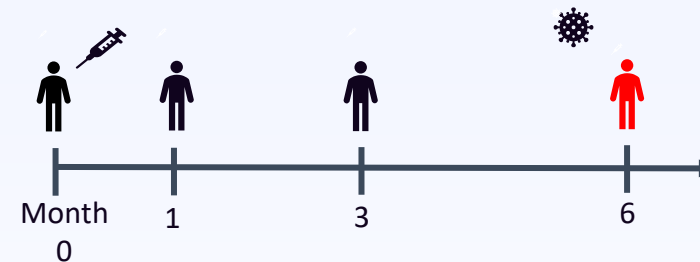
Step 2: Simulate vaccine-induced or hybrid protection

- Vaccine: number doses, timing of last dose
- Prior infection: yes/no, timing of last infection
- Vaccine/hybrid protection data: level of protection and waning curves



Step 3: Calibrate model to data

- Epidemiologic data: COVID-19 severe incidence, seroprevalence
- Calibrated to ~September 2022



Step 4: Run simulation of different vaccine strategies

- Vaccine strategies: One-time (1 dose); Annual (2 doses), Semi-annual (4 doses); Simulate over 2-years
- Simulate person-level waning of protection and COVID-19 at each time step (static infection model)
- Primary study outcome: Absolute annual risk of severe COVID-19

Annual and semiannual COVID-19 vaccine doses likely to have largest benefit in people ages ≥ 65 years and people who are immunocompromised

	Absolute annual risk of severe COVID-19 (cases per 100,000; uncertainty interval)	Annual risk reduction of severe COVID-19		NNT to avert severe COVID-19 case
		Absolute risk (cases per 100,000)	Relative risk (%)	
One-time booster				
18-49 years	98 (85 - 125)	--	--	--
50-64 years	199 (185 - 238)	--	--	--
65-74 years	524 (499 - 562)	--	--	--
75+ years	1,398 (1,332 - 1,501)	--	--	--
Immunocompromised (mild)	1,290 (1,205 - 1,403)	--	--	--
Immunocompromised (moderate/severe)	1,367 (1,266-1,503)	--	--	--
Annual booster				
18-49 years	84 (74 - 106)	14	14%	3,534
50-64 years	171 (159 - 202)	28	14%	1,806
65-74 years	446 (425 - 475)	78	15%	642
75+ years	1,198 (1,144 - 1,272)	199	14%	251
Immunocompromised (mild)	1,180 (1,088 - 1,316)	110	9%	456
Immunocompromised (moderate/severe)	1,183 (1,091-1,307)	184	13%	273
Semiannual booster (every 6 months)				
18-49 years	72 (64 - 90)	26	27%	1,916
50-64 years	147 (136 - 171)	52	26%	968
65-74 years	382 (365-404)	142	27%	353
75+ years	1,030 (988 - 1,088)	368	26%	136
Immunocompromised (mild)	1,095 (987 - 1,255)	195	15%	257
Immunocompromised (moderate/severe)	1,057 (966-1,183)	310	23%	162

COVID-19 vaccine safety

- COVID-19 vaccines have a favorable safety profile as demonstrated by robust safety surveillance over 3 years of COVID-19 vaccine use.
 - Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines.
 - Rare risk of myocarditis and pericarditis, however this is predominately in males ages 12-39 years.
 - No new safety concerns have been identified for the 2023-2024 Formula COVID-19 vaccine.
- Reactogenicity symptoms have been reported following COVID-19 vaccines.
 - Local: Pain at the injection site; less commonly, redness and swelling at the injection site
 - Systemic: Fever, fatigue, headache, chills, myalgia, arthralgia, and diarrhea
 - Overall, symptoms less frequent and severe among older adults compared with adolescents and younger adults.

Review of COVID-19 vaccine and ischemic stroke¹

- A statistical signal for ischemic stroke after Pfizer-BioNTech bivalent mRNA COVID-19 vaccine was detected in CDC's Vaccine Safety Datalink in persons aged ≥ 65 years during fall 2022; information was presented at prior ACIP meetings and efforts have been underway to evaluate the signal.²
- Available data do not provide clear and consistent evidence of a safety problem for ischemic stroke with bivalent mRNA COVID-19 vaccines when given alone or given simultaneously with influenza vaccines.
 - Variable and inconsistent results were obtained in some analyses of the risk of ischemic stroke following bivalent mRNA COVID-19 vaccination, simultaneous bivalent mRNA COVID-19 and influenza vaccination, and influenza vaccination alone.
 - Most study results have not shown an association between vaccination and ischemic stroke, and no clear pattern demonstrating increased risk has emerged.

¹ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/01-VaxSafety-Shimabukuro-508.pdf>

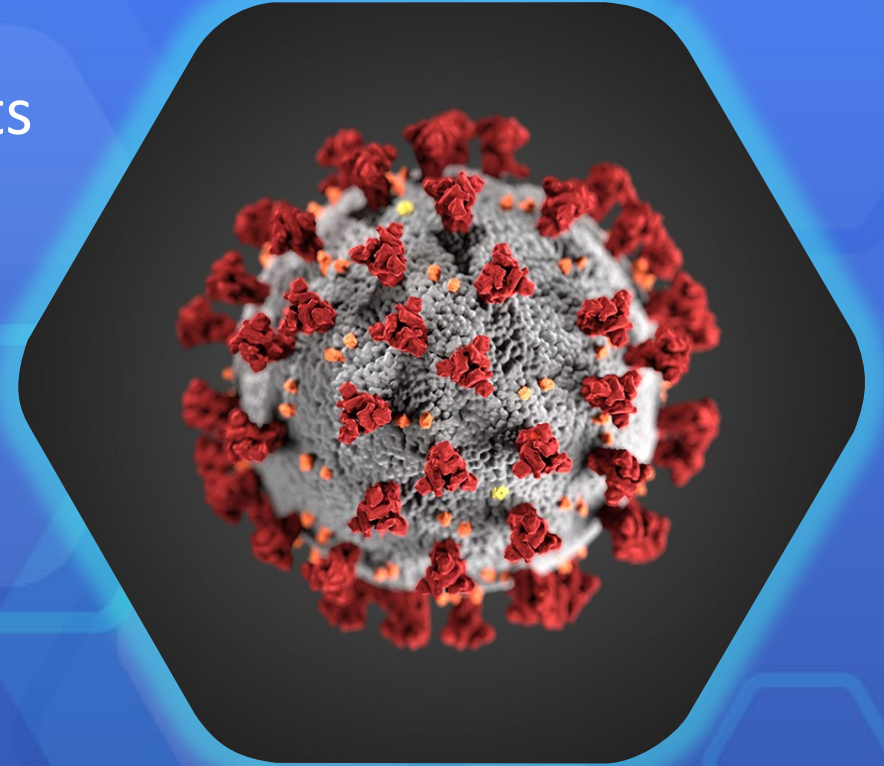
² <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-24/COVID-02-Shimabukuro-508.pdf> and <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-04-19/03-COVID-Shimabukuro-508.pdf>

Review of COVID-19 vaccine and ischemic stroke

- Any real or theoretical risk needs to be placed in the context of the known benefits of COVID-19 vaccination in preventing COVID-19 disease and the potentially serious complications, including stroke.
- Among adults aged ≥ 65 years, a recent bivalent mRNA COVID-19 vaccine dose helped provide protection against COVID-19-related thromboembolic events compared with more distant receipt of original monovalent doses alone.¹

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

- 2023-2024 Formula COVID-19 vaccination provided increased protection against symptomatic SARS-CoV-2 infection and COVID-19-associated ED/UC visits and hospitalizations compared to no updated vaccine dose.
 - COVID-19 vaccine effectiveness from previous vaccine formulations has waned over time but appears more durable against critical illness.
- An additional dose of 2023-2024 Formula may restore vaccine effectiveness which is expected to wane, providing additional protection until the next updated vaccine is available.
- COVID-19 vaccines have a favorable safety profile.
 - Local and systemic symptoms have been reported following receipt of COVID-19 vaccines; however, symptoms are less frequent and severe among older adults compared with adolescents and younger adults.
 - Available data do not provide clear and consistent evidence of a safety issue for ischemic stroke with bivalent mRNA COVID-19 vaccines either when given alone or given simultaneously with influenza vaccines.

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

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

Majority opinion

Minority opinion

Benefits and Harms

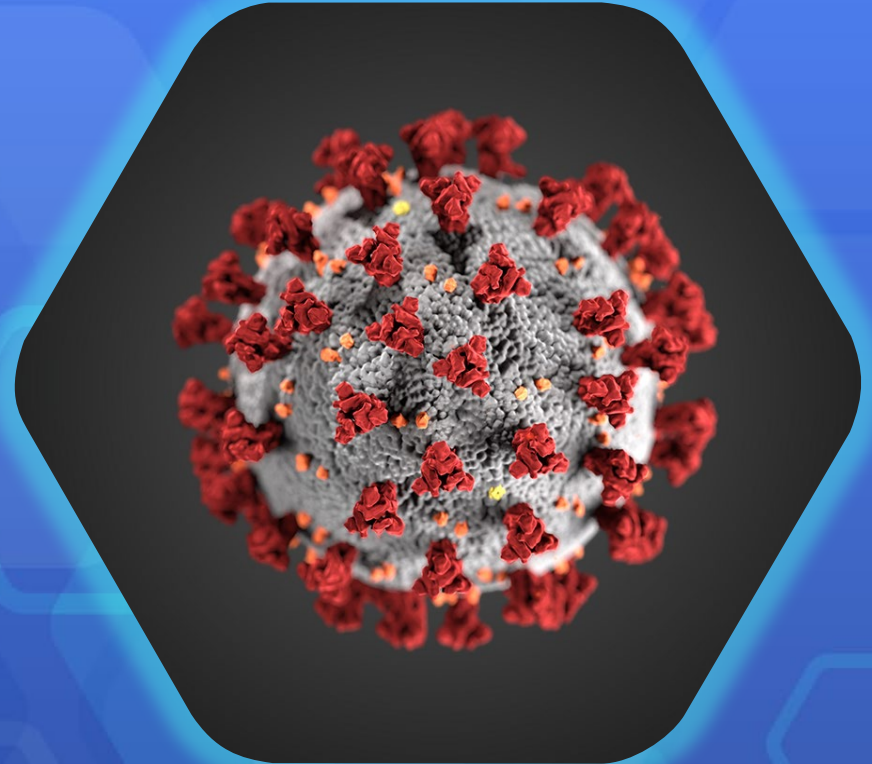
Do the desirable effects outweigh the undesirable effects?

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

- Favors intervention (Additional dose of 2023-2024 Formula COVID-19 vaccine)
- Favors comparison (no vaccine)
- Favors both
- Favors neither
- Unclear

EtR Domain:

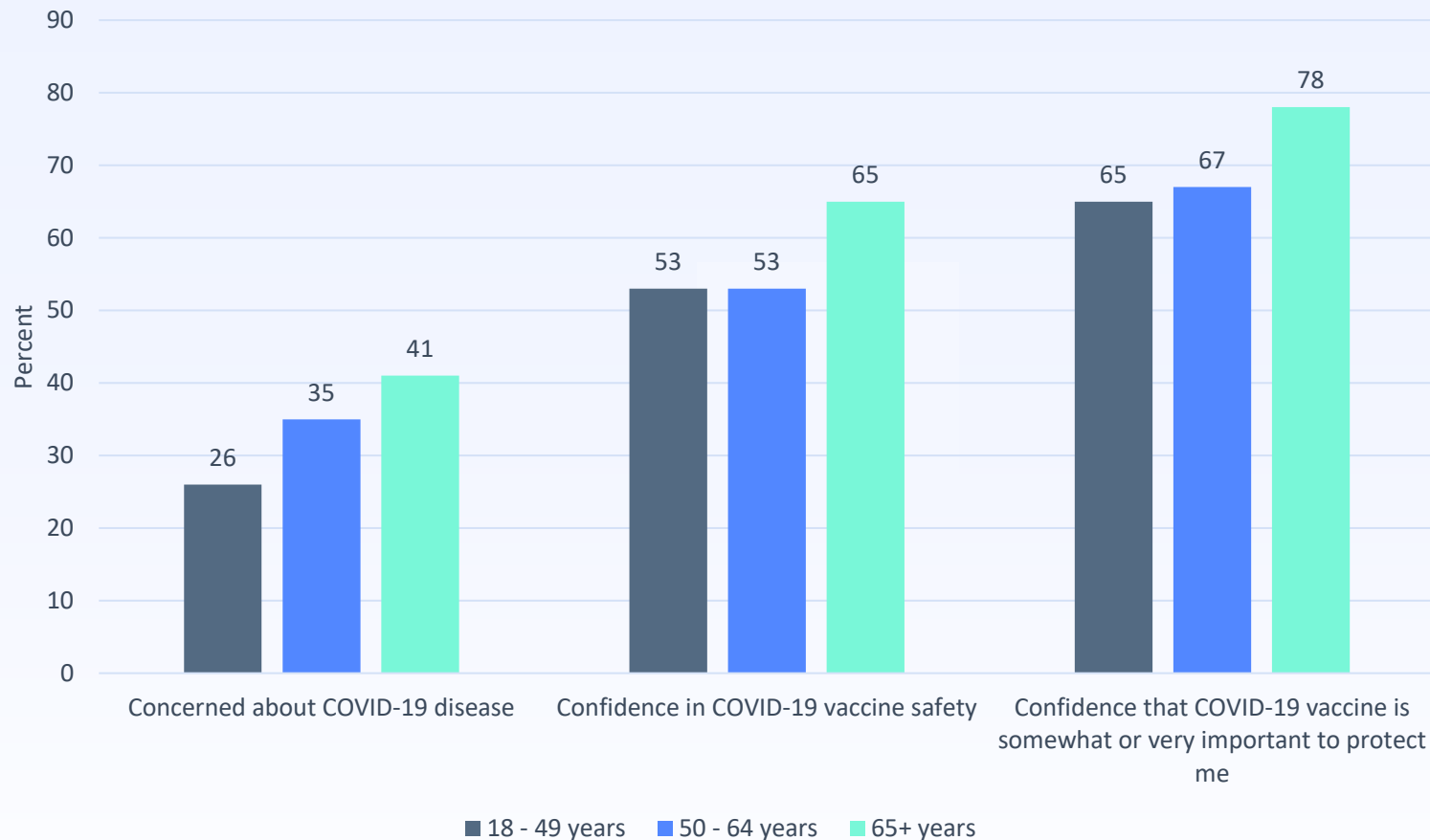
Values



Key attitudes and experiences among adults 18 years and older, December 2023

National Immunization Survey-Adult COVID Module (NIS-ACM)

COVID-19 Vaccination Key Attitudes and Experiences by Age Group
Among Adults Age ≥18 Years, NIS-ACM, December 2023



Adults ages 65 years and older were more concerned about COVID-19 disease and had higher confidence in vaccine safety and vaccine importance; those ages 18 – 49 years and 50 – 64 years were less concerned and confident.

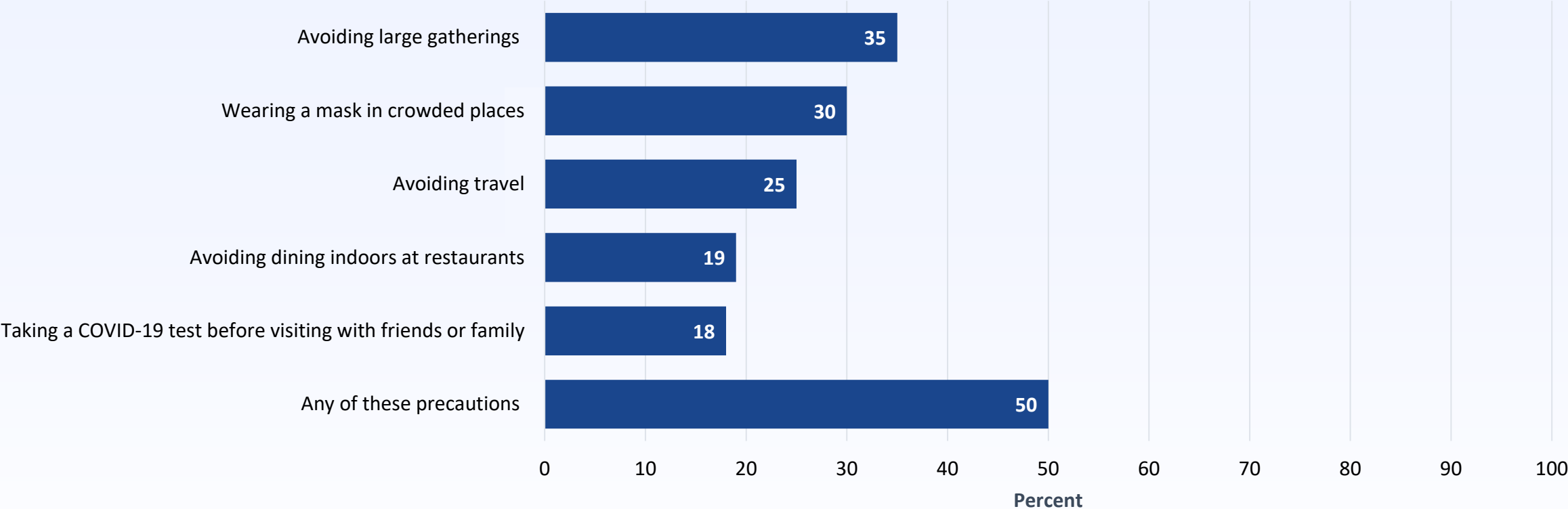
The December estimates are based on data collected November 26 through December 30.

CDC. COVID-19 Vaccination Coverage and Vaccine Confidence Among Adults. <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html>

Accessed February 7, 2024

Half of adults say they are taking precautions because of COVID-19 during the fall and winter months

Percent who say they are taking each of the following precautions because of COVID-19 this fall and winter:



The survey was conducted October 31- November 7, 2023, online and by telephone among a nationally representative sample of 1,301 U.S. adults.

KFF COVID-19 Vaccine Monitor (Oct. 31-Nov. 7, 2023) [KFF COVID-19 Vaccine Monitor November 2023: With COVID Concerns Lagging, Most People Have Not Gotten Latest Vaccine And Half Say They Are Not Taking Precautions This Holiday Season | KFF](#) Accessed November 17, 2023

Precautions against COVID-19 during fall and winter by age

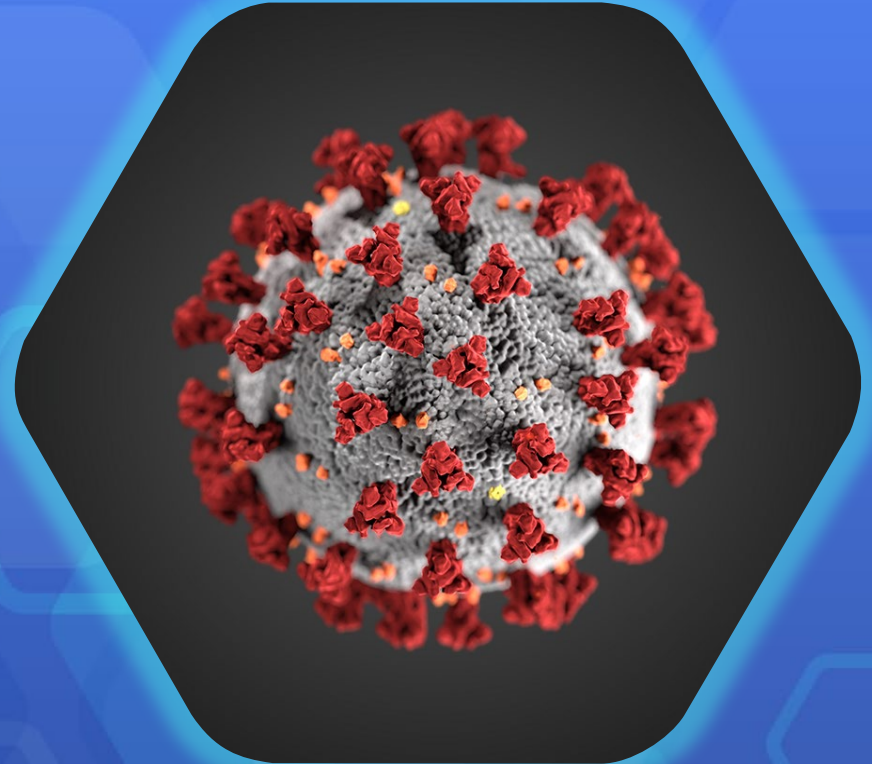
- Similar shares of younger and older adults reported plans to take at least one precaution during the fall and winter.
- However, four in ten (**41%**) adults ages 65 and older said they plan to avoid large gatherings, compared to a third (**33%**) of those under the age of 65.
- While younger adults were less likely to say they will avoid large gatherings, **21%** of those <65 years say they will take a test for COVID-19 before spending time with friends or family compared to **10%** of those ages 65 and older.

The survey was conducted October 31- November 7, 2023, online and by telephone among a nationally representative sample of 1,301 U.S. adults.

KFF COVID-19 Vaccine Monitor (Oct. 31-Nov. 7, 2023) [KFF COVID-19 Vaccine Monitor November 2023: With COVID Concerns Lagging, Most People Have Not Gotten Latest Vaccine And Half Say They Are Not Taking Precautions This Holiday Season](#) | KFF Accessed November 17, 2023

Domain Equity Question:

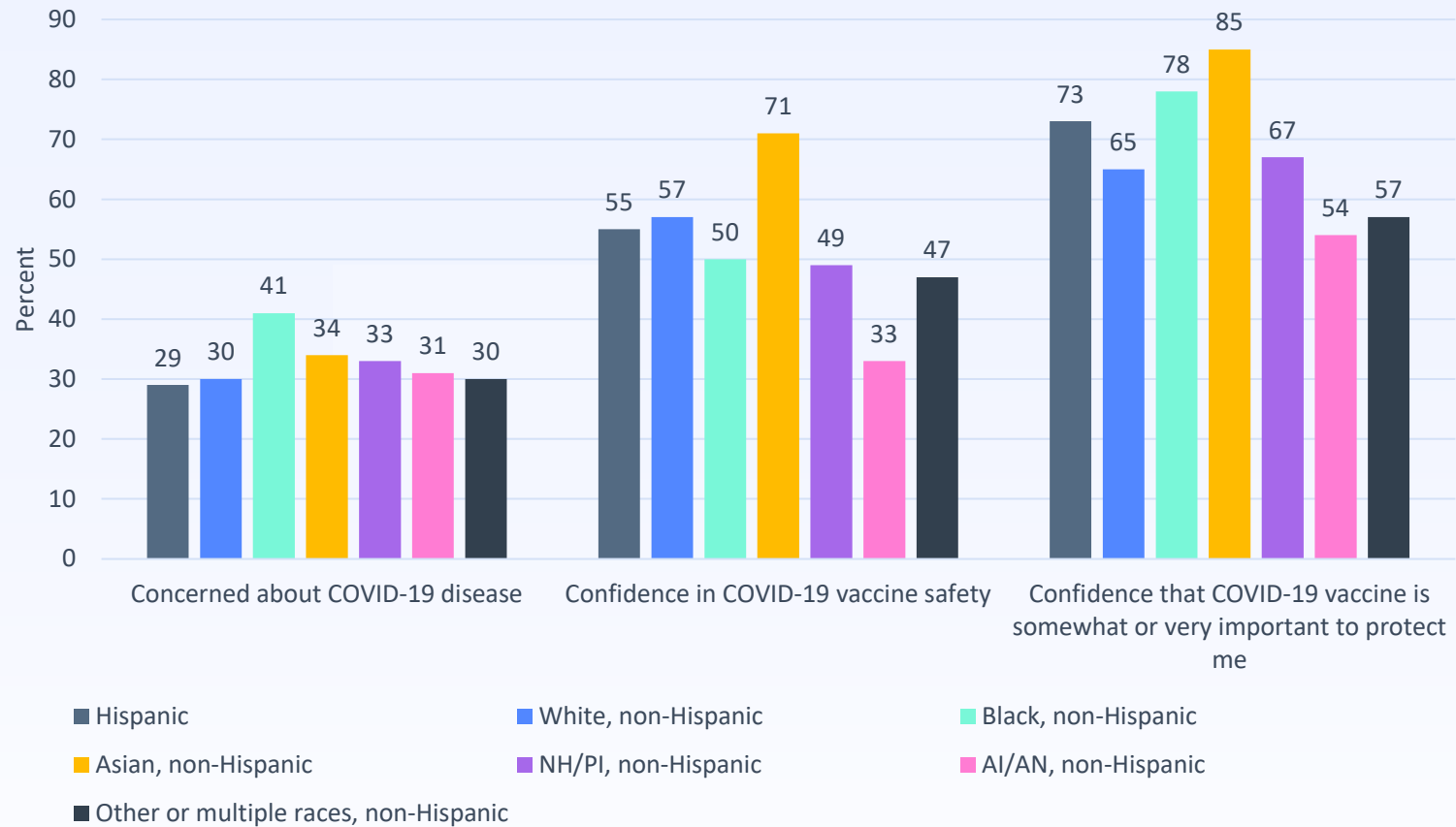
Is there important variability in how patients or populations value the outcome?



Key attitudes and experiences among adults 18 years and older, December 2023

National Immunization Survey-Adult COVID Module (NIS-ACM)

COVID-19 Vaccination Key Attitudes and Experiences by Race & Ethnicity
Among Adults Age ≥18 Years, NIS-ACM, December 2023

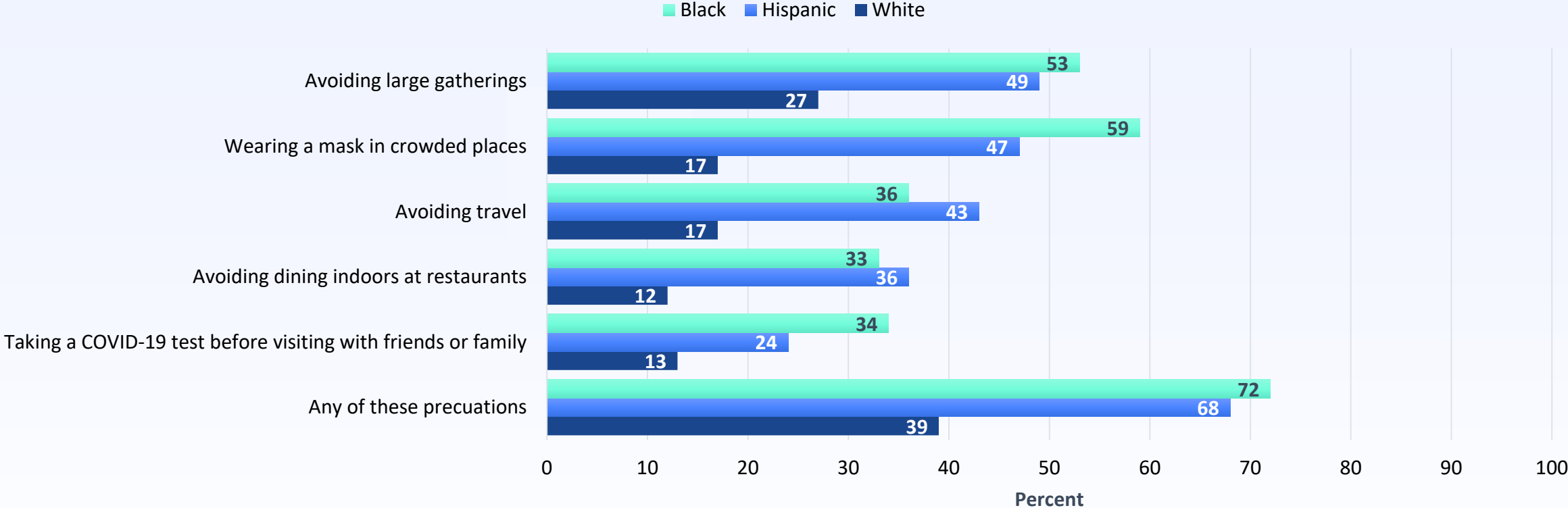


AI/AN: American Indian or Alaska Native; NH/PI: Native Hawaiian or Other Pacific Islander
The December estimates are based on data collected November 26 through December 30.

CDC. COVID-19 Vaccination Coverage and Vaccine Confidence Among Adults. <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html>
Accessed February 7, 2024

Precautions against COVID-19 during fall and winter by race and ethnicity

Percent who say they are taking each of the following precautions because of COVID-19 this fall and winter:



The survey was conducted October 31- November 7, 2023, online and by telephone among a nationally representative sample of 1,301 U.S. adults.

Summary

Values

- Adults ages 65 years and older were more concerned about COVID-19 disease and had higher confidence in vaccine safety and vaccine importance than those <65 years.
 - Black adults were more concerned about COVID-19 disease than people of other racial and ethnic groups.
 - Confidence in COVID-19 vaccine safety and importance varied by racial and ethnic group.
- Half of adults reported plans to take precautions because of COVID-19 during the fall and winter months, with 41% of adults ages ≥ 65 years planning to avoid large gatherings.
 - Larger proportions of Black and Hispanic adults report they plan to take precautions against COVID-19 than White adults.

Values

Criteria 1:

Do older adults feel that the desirable effects are large relative to undesirable effects?

- How do older adults view the balance of desirable versus undesirable effects?
- Would older adults feel that the benefits outweigh the harms?

Minimal

Small

Moderate

Large

Varies

Don't know

Values

Criteria 2:

Is there important uncertainty about, or variability in, how older adults value the main outcomes?

- 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

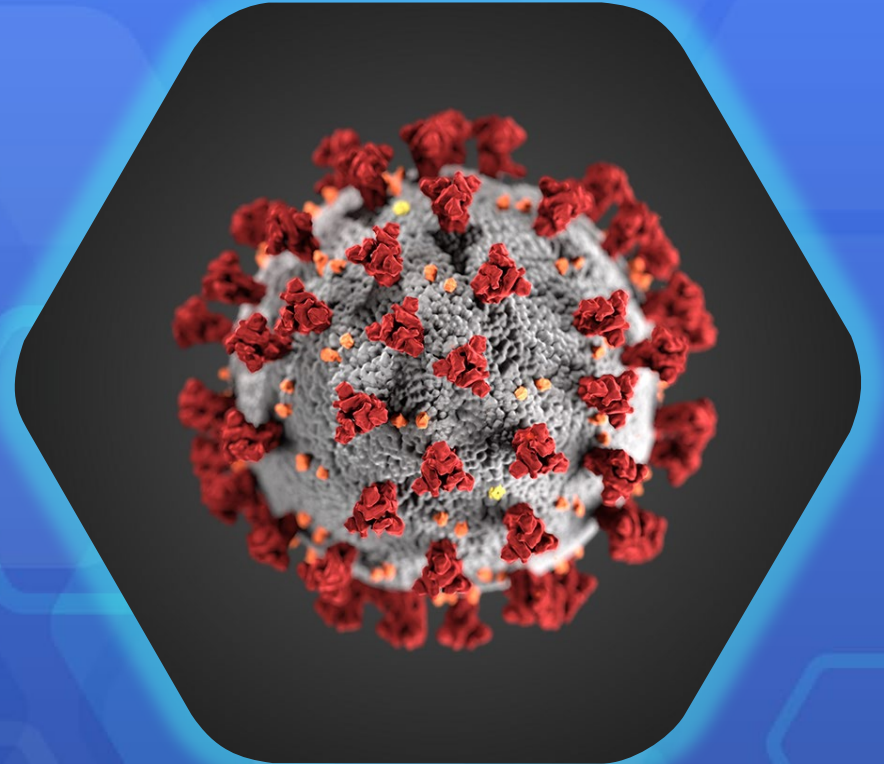
No important uncertainty or variability

No known undesirable outcomes

Majority opinion

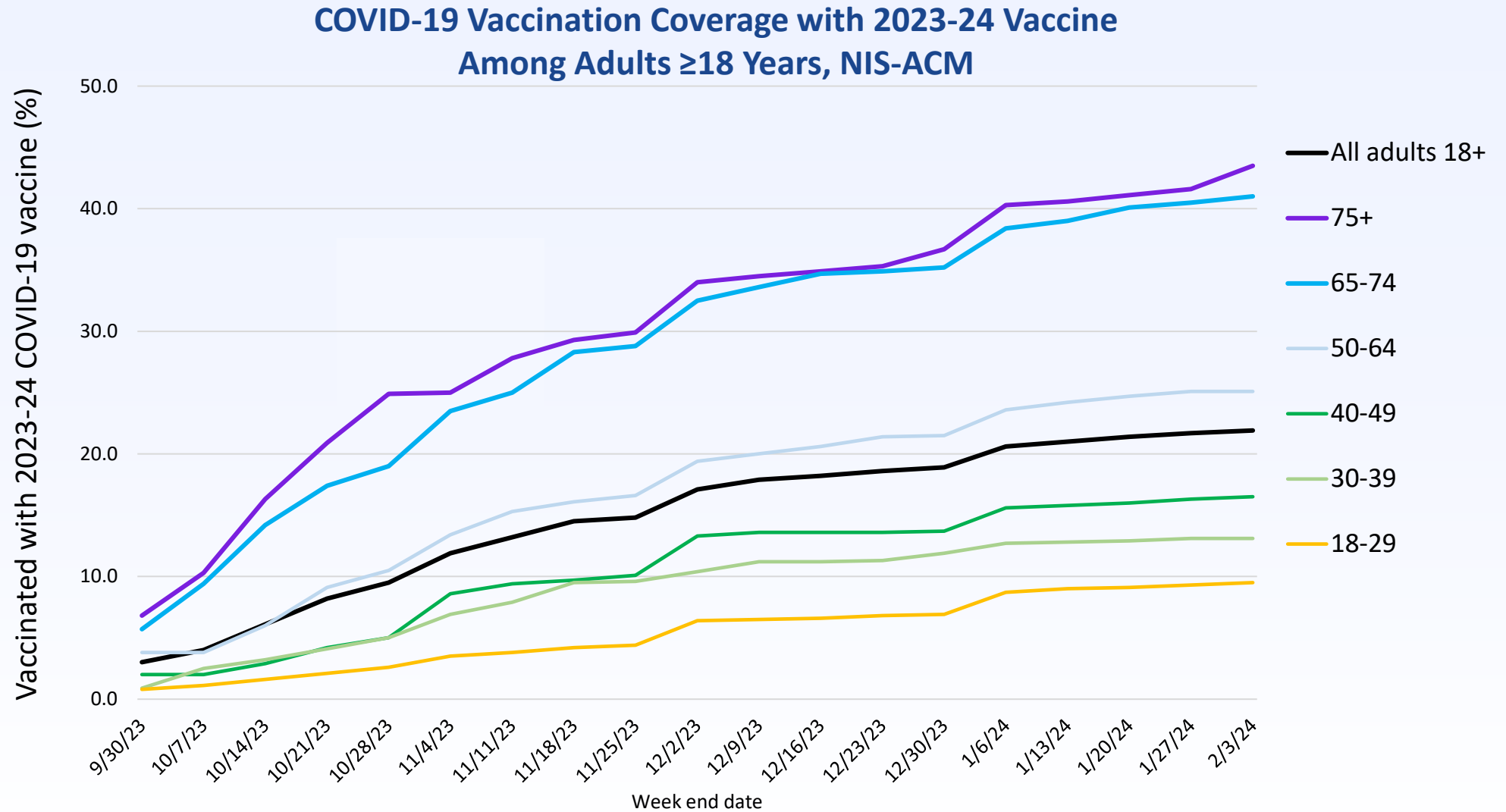
Minority opinion

EtR Domain: Acceptability

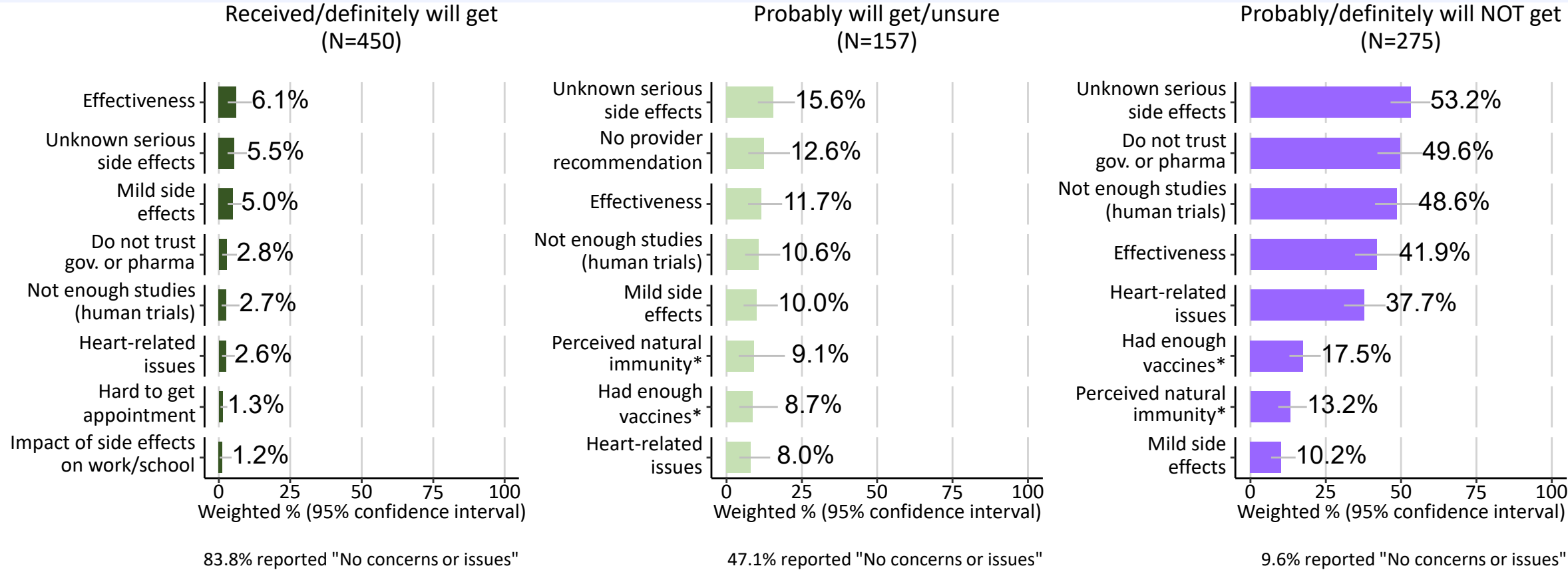


Percent vaccinated with 2023-24 COVID-19 vaccine

National Immunization Survey-Adult COVID Module (NIS-ACM)



Top COVID-19 vaccination concerns and issues among adults ≥65 years of age, by status/intent, Omnibus Surveys, January 5 – 29, 2024 (N=882)



Other response options included: "Too busy or kept forgetting," "Cost/time concerns," "Unsure if eligible," "Fertility issues," "HCP recommended against," "Other concern."

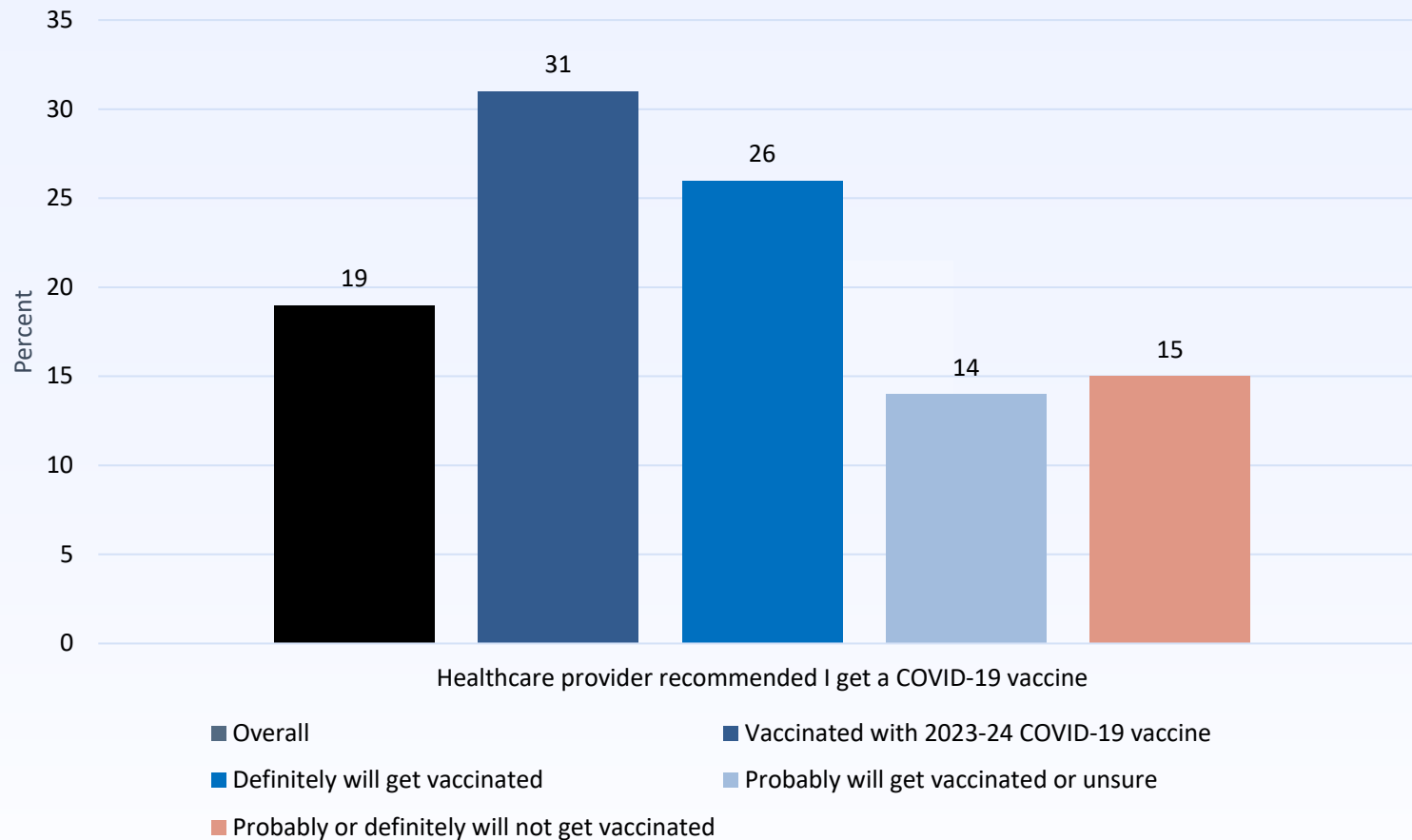
*Option not offered to those who already received the vaccine.

Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults aged 18 years and older. CDC fields questions about vaccination status, intent, knowledge, attitudes, beliefs, and behaviors on each survey for 2 waves each month, for a combined sample size of ~4,000 respondents. These slides present results from January (N=4,287). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

Key attitudes and experiences among adults 18 years and older, December 2023

National Immunization Survey-Adult COVID Module (NIS-ACM)

COVID-19 Vaccination Key Attitudes and Experiences by Vaccination Status
Among Adults Age ≥18 Years, NIS-ACM, December 2023



19% of adults received a healthcare provider vaccine recommendation; highest among adults who were vaccinated or definitely plan to get vaccinated.

The December estimates are based on data collected November 26 through December 30.

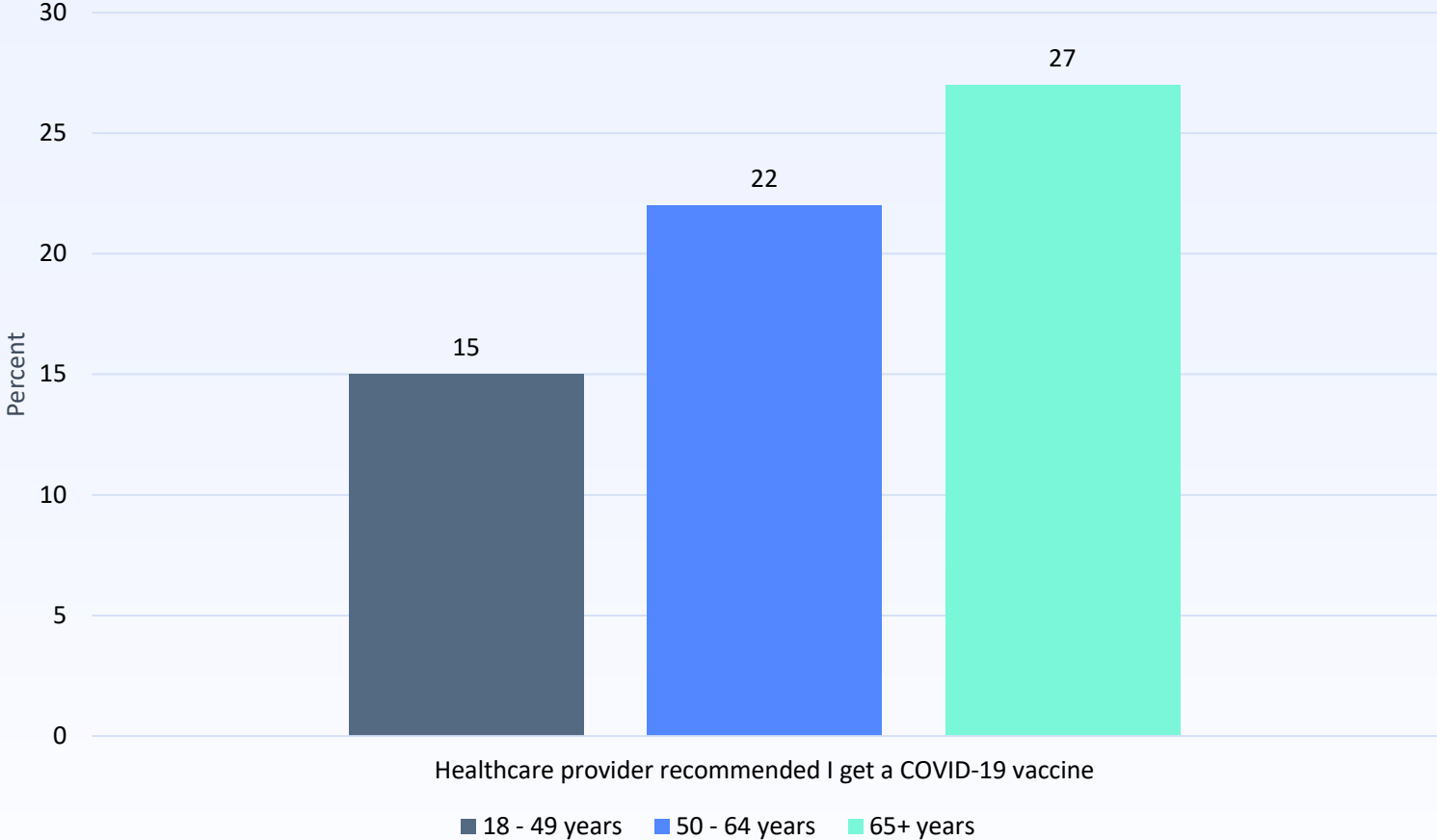
CDC. COVID-19 Vaccination Coverage and Vaccine Confidence Among Adults. <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html>

Accessed February 7, 2024

Key attitudes and experiences among adults 18 years and older, December 2023

National Immunization Survey-Adult COVID Module (NIS-ACM)

COVID-19 Vaccination Key Attitudes and Experiences by Age Group
Among Adults Age ≥18 Years, NIS-ACM, December 2023

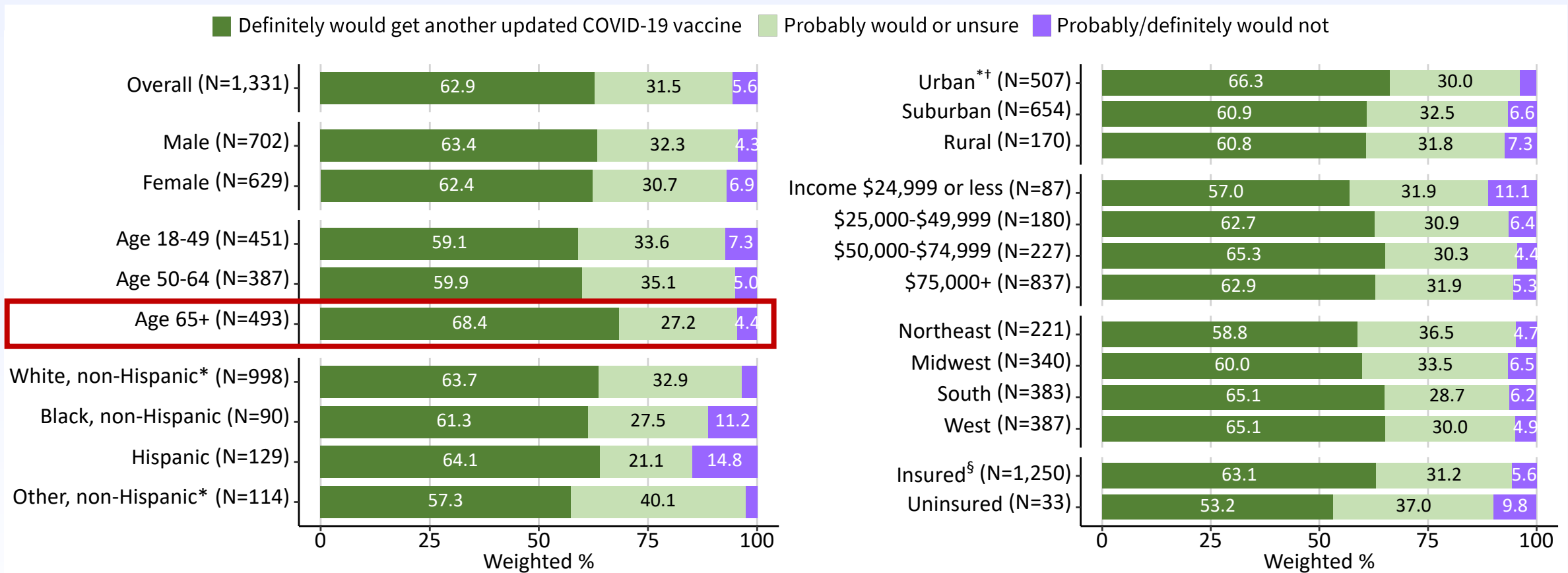


Healthcare provider recommendation was highest among adults ages ≥65 years.

The December estimates are based on data collected November 26 through December 30.

CDC. COVID-19 Vaccination Coverage and Vaccine Confidence Among Adults. <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html>
Accessed February 7, 2024

Intent to receive *additional* COVID-19 vaccine dose among adults ≥18 years of age who received a dose since September 14, 2023, Omnibus Surveys, November 30, 2023-January 16, 2024 (N=1,331)

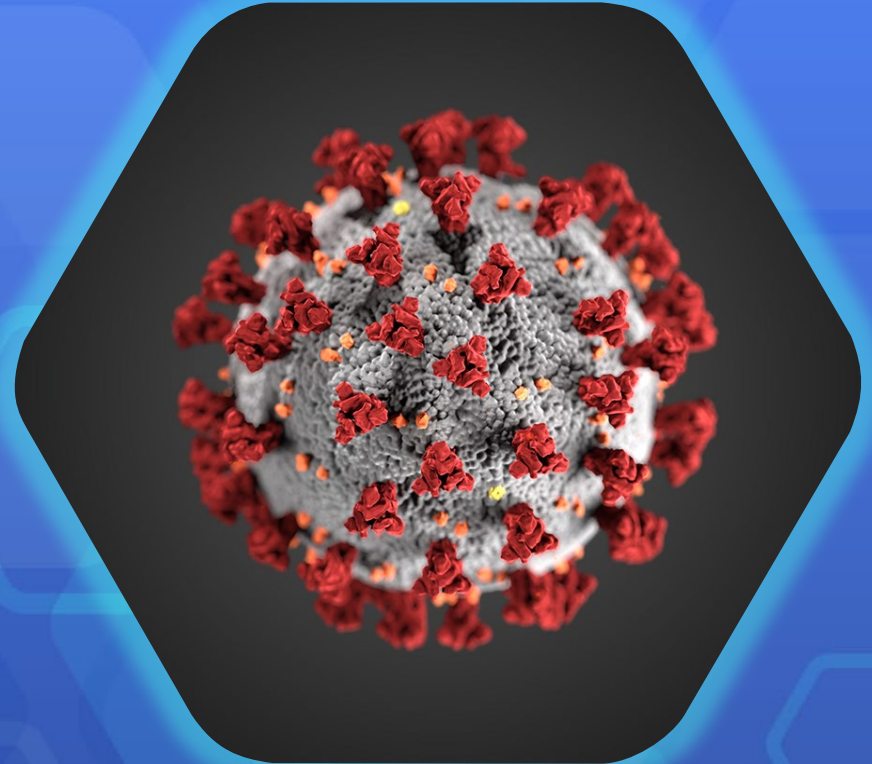


*Labels for estimates <4% not shown. **NORC and Ipsos base urbanicity on different, but comparable measures. NORC uses Census tract-based RUCA (Rural-Urban-Commuting Area) codes, whereas Ipsos uses Office of Management and Budget's CBSA (Core Based Statistical Area) classification. [§]Includes plans purchased through employer, insurance companies, marketplaces, military insurance, Medicare, Medicaid, VA, IHS, and "other."

Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults aged 18 years and older. CDC fields questions about vaccination status, intent, knowledge, attitudes, beliefs, and behaviors on each survey for 2 waves each month, for a combined sample size of ~4,000 respondents. These slides present results from January (N=4,287). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

Domain Equity Question:

Is the intervention equally acceptable across all populations?

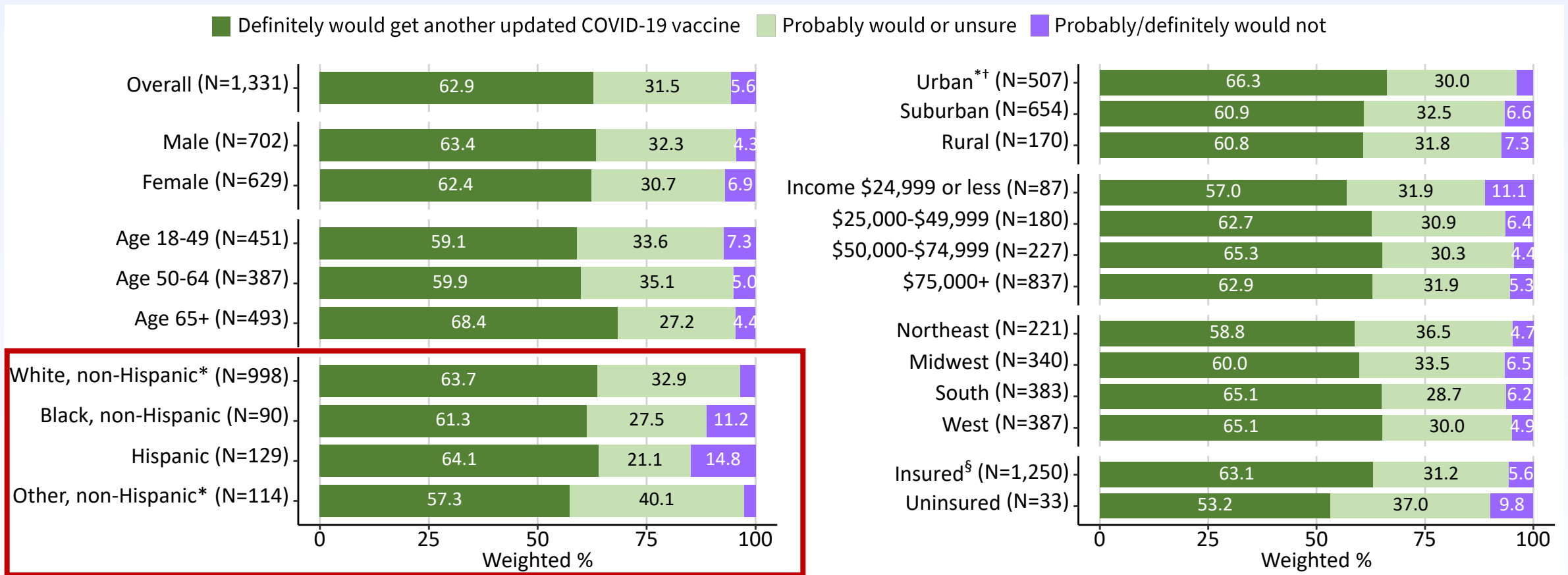


Is the intervention equally acceptable across all populations?

Among adults age ≥ 18 years responding to the NIS-ACM during Nov. 26 – Dec. 30, 2023:

- Vaccination coverage differed by race/ethnicity.
 - Coverage was highest among White, non-Hispanic adults and lowest among American Indian/Alaska Native and Native Hawaiian/Other Pacific Islander adults.
- Vaccination coverage was higher in urban and suburban areas compared with rural areas.
- Adults with health insurance had significantly higher vaccination coverage than adults without insurance.
- Vaccination coverage increased with increasing household income.

Intent to receive *additional* COVID-19 vaccine dose among adults ≥18 years of age who received a dose since September 14, 2023, Omnibus Surveys, November 30, 2023-January 16, 2024 (N=1,331)



*Labels for estimates <4% not shown. **NORC and Ipsos base urbanicity on different, but comparable measures. NORC uses Census tract-based RUCA (Rural-Urban-Commuting Area) codes, whereas Ipsos uses Office of Management and Budget's CBSA (Core Based Statistical Area) classification. [§]Includes plans purchased through employer, insurance companies, marketplaces, military insurance, Medicare, Medicaid, VA, IHS, and "other."

Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults aged 18 years and older. CDC fields questions about vaccination status, intent, knowledge, attitudes, beliefs, and behaviors on each survey for 2 waves each month, for a combined sample size of ~4,000 respondents. These slides present results from January (N=4,287). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

Summary

Acceptability

- As of February 2024, vaccination coverage with 2023-2024 COVID-19 vaccine was highest among older adults ages 65 – 74 years and 75+ years, compared to younger age groups.
 - Disparities in COVID-19 vaccine coverage are observed across many demographic factors, including race, ethnicity, insurance status and rurality.
- Adults who were vaccinated or definitely plan to get vaccinated were more likely to report that a healthcare provider recommended they get a COVID-19 vaccine.
 - Adults ≥ 65 years were more likely to report a healthcare provider recommendation than younger adults.
- Among adults ≥ 65 years of age who had already received a 2023-2024 Formula COVID-19 vaccine dose, 68.4% reported they definitely will get an additional dose of 2023-2024 Formula COVID-19 vaccine if it is recommended for them.

Acceptability

Would recommending an additional dose of 2023-2024 Formula COVID-19 vaccine for older adults be 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?

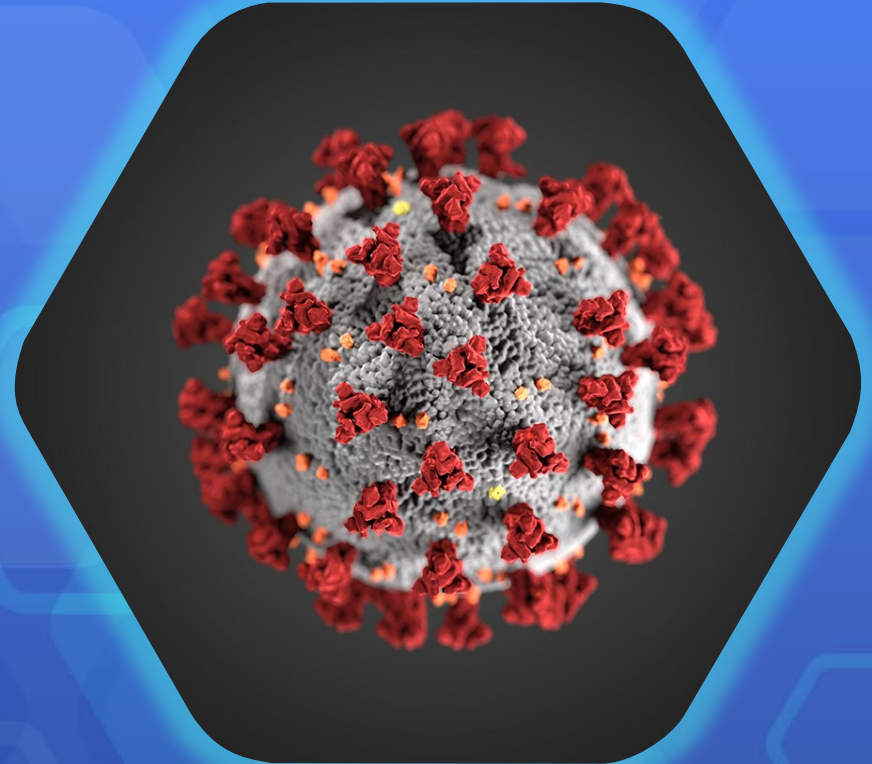
No Probably no Probably yes Yes Varies Don't know

Majority opinion

Minority opinion

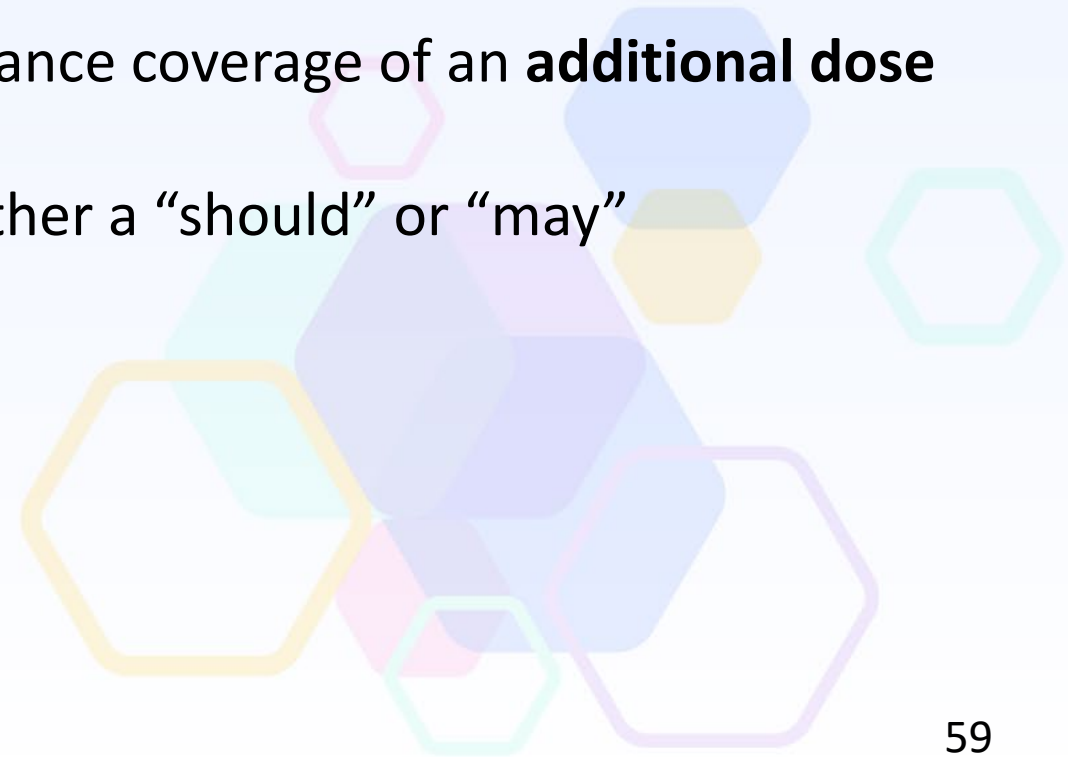
EtR Domain:

Feasibility



Financial Barriers

- COVID-19 vaccines are now available on the commercial market.
 - COVID-19 vaccines are covered by private and public insurance and available through the Bridge Access Program and Vaccines for Children for those that are uninsured or underinsured.
- ACIP recommendation would be needed for insurance coverage of an **additional dose** of 2023-2024 Formula COVID-19 vaccine.
 - Insurance coverage generally required under either a “should” or “may” recommendation.

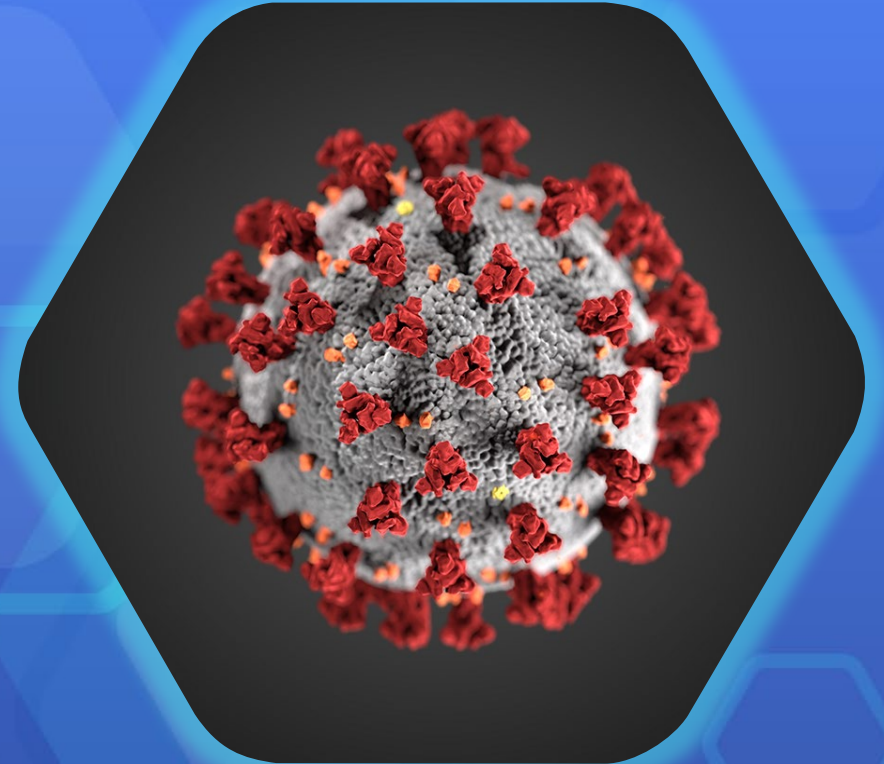


Implementation and vaccine access

- Additional dose recommendation would be for same formula (2023-2024) of COVID-19 vaccine that is currently available.
 - Existing COVID-19 vaccine administration infrastructure and product can be used.
 - Age-based recommendation would not be overly burdensome to implement.
- Additional dose recommendation in those ≥ 65 years would add complexity to COVID-19 vaccine recommendations which have been getting simpler.
 - Frequent changes to vaccine recommendations can lead to vaccine fatigue.
 - Systems are already planning for next season, and adding more recommendations for this year could add additional burden to an already fatigued system.
 - Minimum interval of 4 months used for additional dose recommendations may confuse providers accustomed to 2 month interval from the fall dose.
 - Providers would need to consider anticipated availability of updated vaccine next fall when considering providing vaccine doses during the summer months.

Domain Equity Question:

Is the intervention equally feasible to implement across all populations?



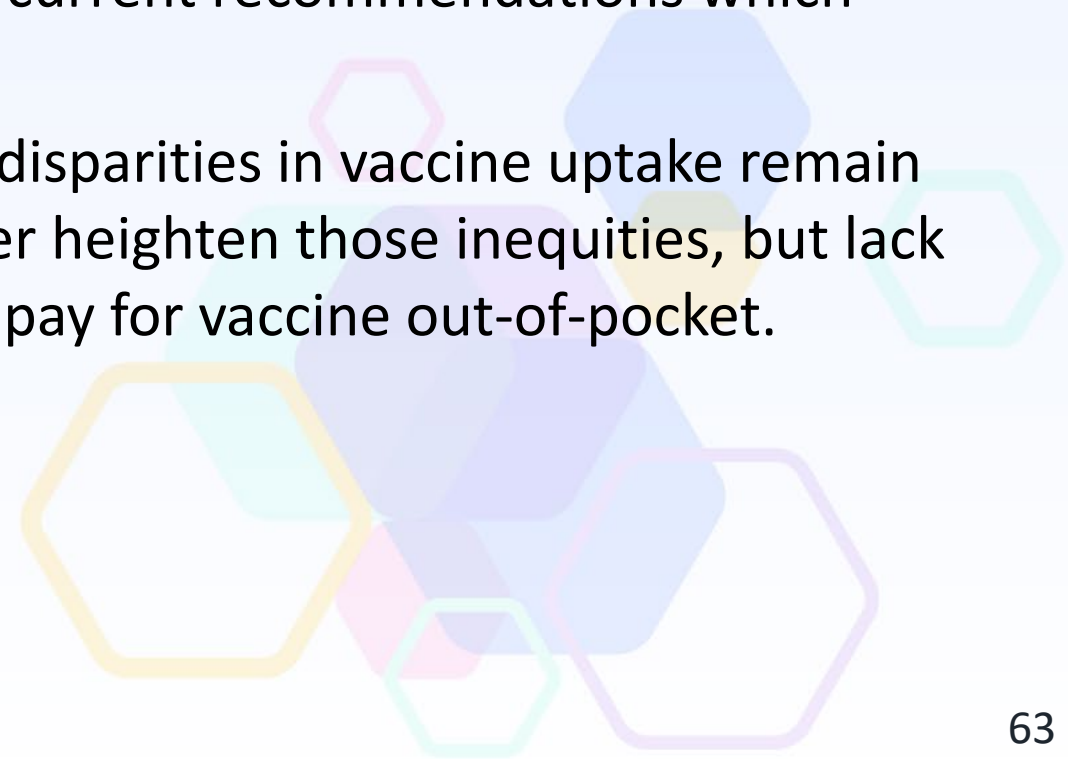
Implementation equity considerations

- Past reports of sites being unaware of additional dose recommendations or requiring documentation to prove eligibility for additional vaccine dose.
 - Wide communication of any change in recommendations and that self-attestation is appropriate will be important to decrease barriers.
- The Bridge Access Program was designed to remove patient barriers to COVID-19 vaccines, however disparities in vaccine uptake by insured status continue.
- To the extent that existing disparities in vaccine uptake by characteristics such as race/ethnicity, urbanicity, and income are driven by differences in vaccine access, additional dose recommendations may further increase those disparities.
 - Access issues may be increased during a time when there are fewer off-site vaccination clinics, which are more common during fall vaccine roll-outs.
- In the absence of an ACIP recommendation, additional doses might be an out-of-pocket cost, therefore those able to pay for an additional dose may have access while others do not.

Summary

Feasibility

- COVID-19 vaccines currently on the commercial market and an ACIP recommendation (should or may) would be needed for insurance coverage of an additional dose.
- Additional dose recommendation would leverage existing infrastructure and vaccine product; however, it would add complexity to the current recommendations which could enhance vaccine and system fatigue.
- Access related barriers to COVID-19 vaccines and disparities in vaccine uptake remain and additional dose recommendations may further heighten those inequities, but lack of recommendation limits access to those able to pay for vaccine out-of-pocket.



Feasibility

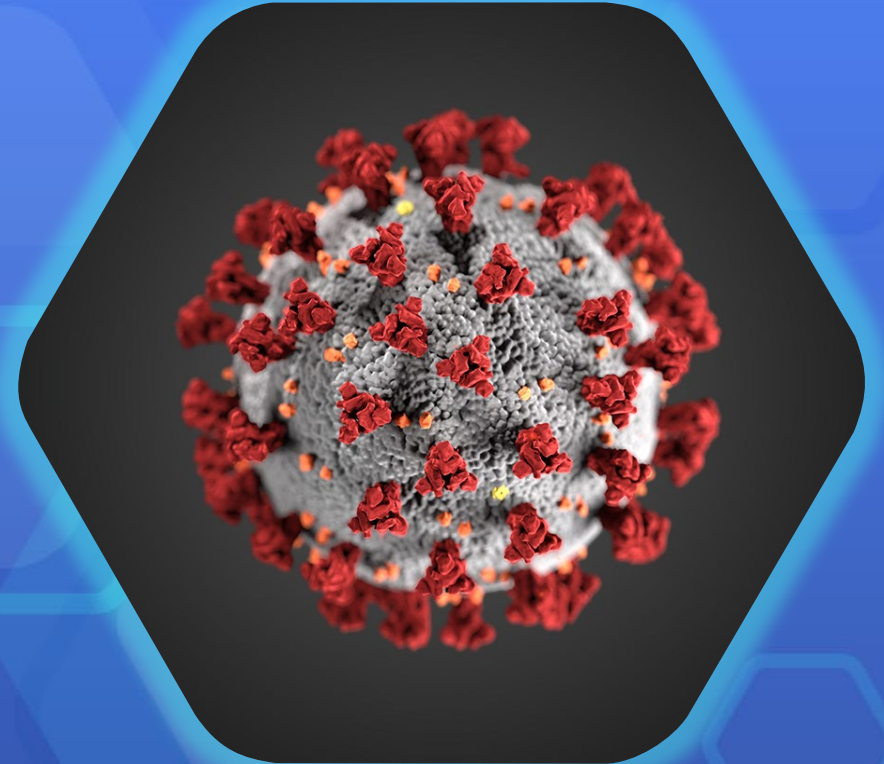
Is an additional dose of the 2023-2024 Formula COVID-19 vaccine feasible to implement among older adults?

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

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

EtR Domain:

Resource Use



Scenario analysis: probability of hospitalization¹, societal perspective

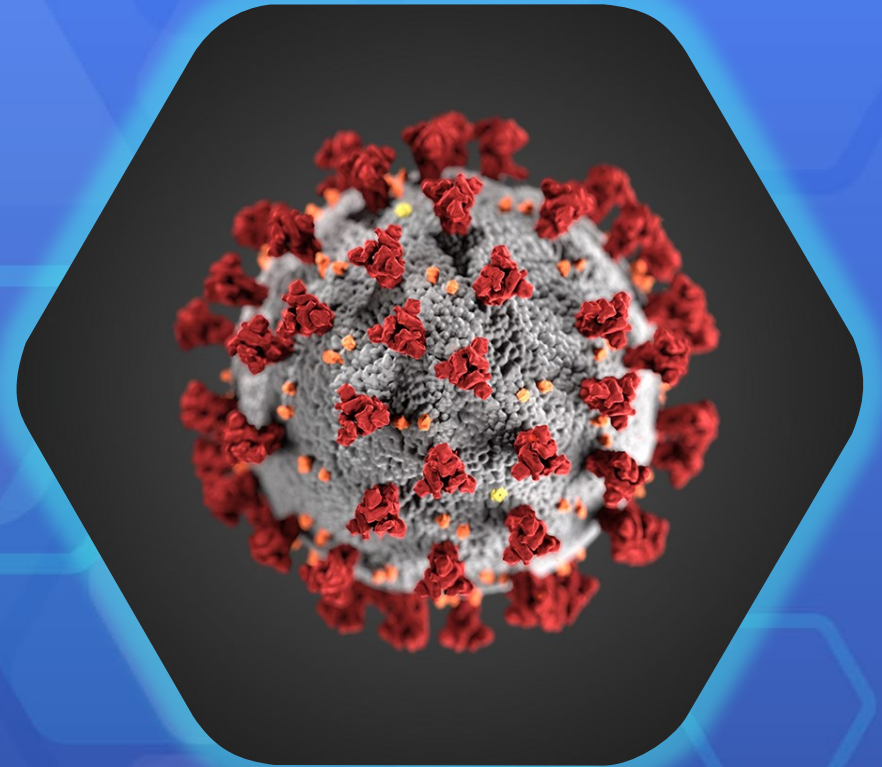
ICER (\$/QALY)							
Age group	Strategy	Base case	¼ base case	½ base case	2x base case	3x base case	4x base case
65+ y	Updated Covid-19 vax, 1 dose	\$11,936	\$93,904	\$52,541	Cost saving	Cost saving	Cost saving
	Updated Covid-19 vax, 2 doses	\$255,122	\$624,028	\$433,533	\$120,341	\$64,599	\$34,133

ICER=Incremental cost effectiveness ratio; QALY=Quality-adjusted life year

¹ From Ko et al 2021. Adjusted risk of hospitalization by underlying condition: chronic obstructive pulmonary disease: 0.9, history of stroke: 0.9, coronary artery disease: 1.3, asthma: 1.4, hypertension: 2.8, obesity: 2.9, diabetes: 3.2, chronic kidney disease: 4.0, severe obesity: 4.4.

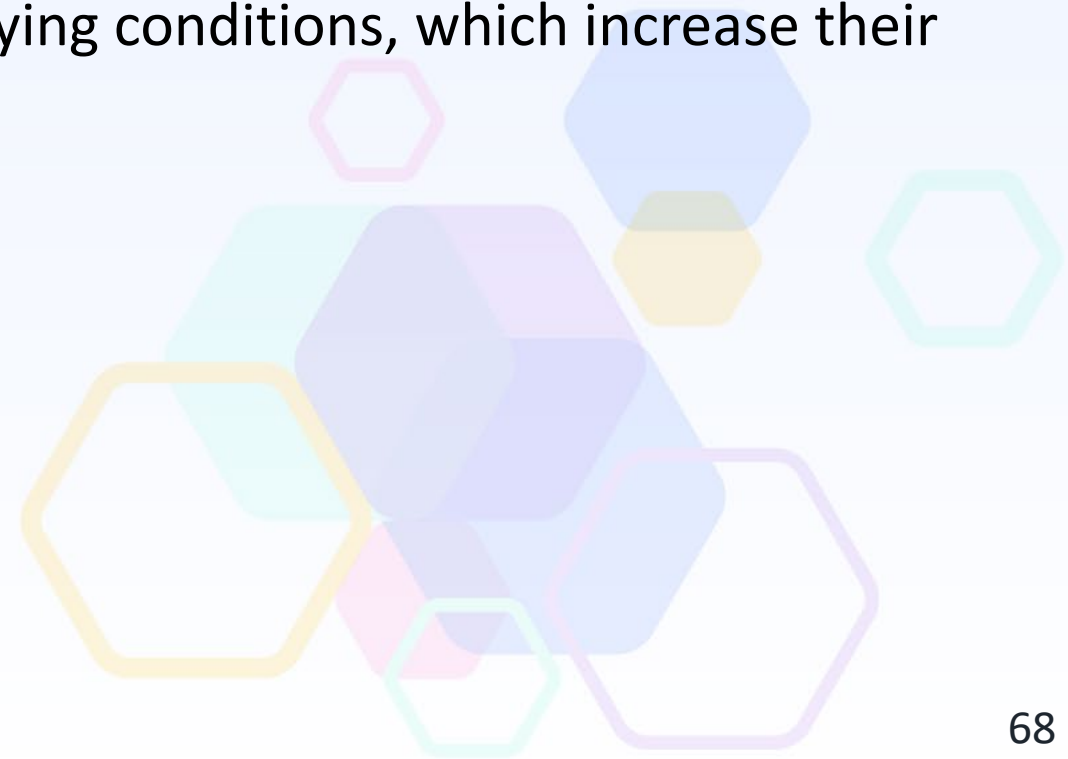
Domain Equity Question:

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?

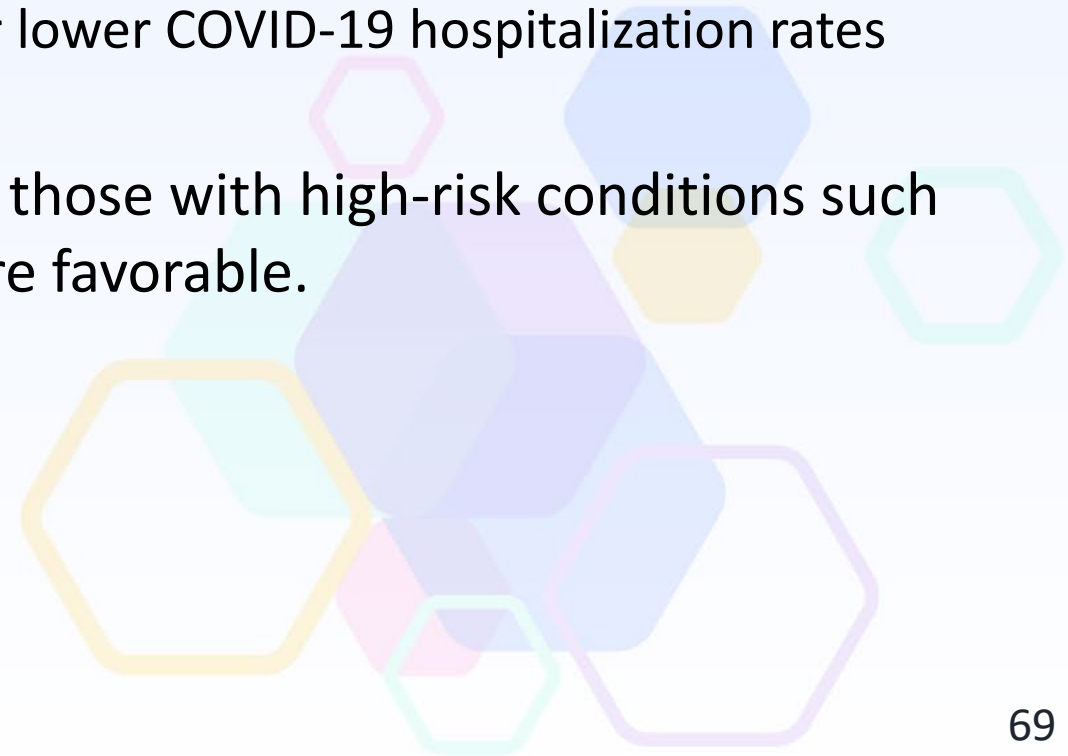
- An additional dose of COVID-19 vaccine is most cost-effective in older adults in which disease burden is highest compared to younger adults.
- An additional dose of COVID-19 vaccine is likely more cost-effective in populations with a higher prevalence of risk factors, such as underlying conditions, which increase their probability of hospitalization due to COVID-19.



Resource Use

Summary

- The cost effectiveness of an additional dose in older adults is highly sensitive to COVID-19-associated hospitalization rates and anticipated rates in the coming months are uncertain.
 - COVID-19-associated hospitalization rates in older adults that are higher than those seen last year would increase the cost effectiveness, however lower COVID-19 hospitalization rates would decrease the cost effectiveness.
- Estimates that approximate cost-effectiveness for those with high-risk conditions such as underlying conditions or advanced age are more favorable.



Resource Use

Is an additional dose of the 2023-2024 Formula COVID-19 vaccine in older adults a reasonable and efficient allocation of resources?

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

No Probably no Probably yes Yes Varies Don't know

Summary and Work Group Interpretations

The background of the slide is a solid blue color. Overlaid on this background is a pattern of hexagons. Some hexagons are solid and semi-transparent, while others are just outlines. The hexagons are arranged in a somewhat random, overlapping pattern across the entire slide.

Summary and Work Group Interpretations

- Greatest benefit of a vaccine dose would be in those who have not yet received a 2023-2024 Formula dose, particularly older adults and those with underlying medical conditions.
 - Data presented today emphasized the importance of any dose of updated (2023-2024 Formula) COVID-19 vaccine in older adults.
- Risk of severe illness due to COVID-19 continues throughout the year and is highest in those ≥ 65 years.
 - Within the ≥ 65 -year age group, risk increases with increasing age.
- Receipt of 2023-2024 Formula COVID-19 vaccine provides protection against JN.1 and other circulating variants, however vaccine effectiveness is expected to wane.
 - In the past, we have seen greater durability in the protection against critical illness.

Summary and Work Group Interpretations

- “May” recommendation would provide flexibility for older adults to obtain an additional dose if they or their healthcare provider feel they would benefit.
 - Most benefit would likely be in those with underlying medical conditions, advanced age, or circumstances that may increase risk (e.g., nursing home resident).
- Additional dose in adults ≥ 65 years may restore protection that has waned.
 - Smaller, incremental benefit on top of the protection still being provided by the initial 2023-2024 Formula COVID-19 vaccine dose.
- Cost effectiveness of an additional dose depends on COVID-19 hospitalization rates in the coming months and the patient risk factors for severe illness due to COVID-19.
- As COVID-19 epidemiology changes with time, additional dose recommendations may not be needed in the future.

Considerations for an additional dose recommendation

Pros	Cons
<ul style="list-style-type: none">• “May” recommendation would provide flexibility for those ≥ 65 years to get an additional dose if they or their healthcare provider feel they would benefit.	<ul style="list-style-type: none">• Smaller, incremental benefit compared to that from initial 2023-2024 COVID-19 vaccine dose in the fall.
<ul style="list-style-type: none">• Restore vaccine effectiveness that may have waned since the initial 2023-2024 COVID-19 vaccine dose.	<ul style="list-style-type: none">• May decrease vaccine confidence in the benefits of a single dose of 2023-2024 COVID-19 vaccine.
<ul style="list-style-type: none">• Acknowledges that risk of severe illness due to COVID-19 continues throughout the year for older adults, despite upticks during winter months.	<ul style="list-style-type: none">• Additional recommendations may increase vaccine fatigue, potentially reducing uptake of vaccine next fall.

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 disease among persons ages 65 years and older of public health importance?	Yes
Benefits and Harms	How substantial are the desirable anticipated effects?	Moderate
	How substantial are the undesirable anticipated effects?	Small
	Do the desirable effects outweigh the undesirable effects?	Favors intervention
Values	Do older adults feel that the desirable effects are large relative to undesirable effects?	Large
	Is there important uncertainty about, or variability in, how older adults value the main outcomes?	Probably important uncertainty or variability
Acceptability	Would recommending an additional dose of 2023-2024 Formula COVID-19 vaccine for older adults be acceptable to key stakeholders?	Probably yes
Feasibility	Is an additional dose of the 2023-2024 Formula COVID-19 vaccine feasible to implement among older adults?	Probably yes
Resource Use	Is an additional dose of the 2023-2024 Formula COVID-19 vaccine a reasonable and efficient allocation of resources?	Probably 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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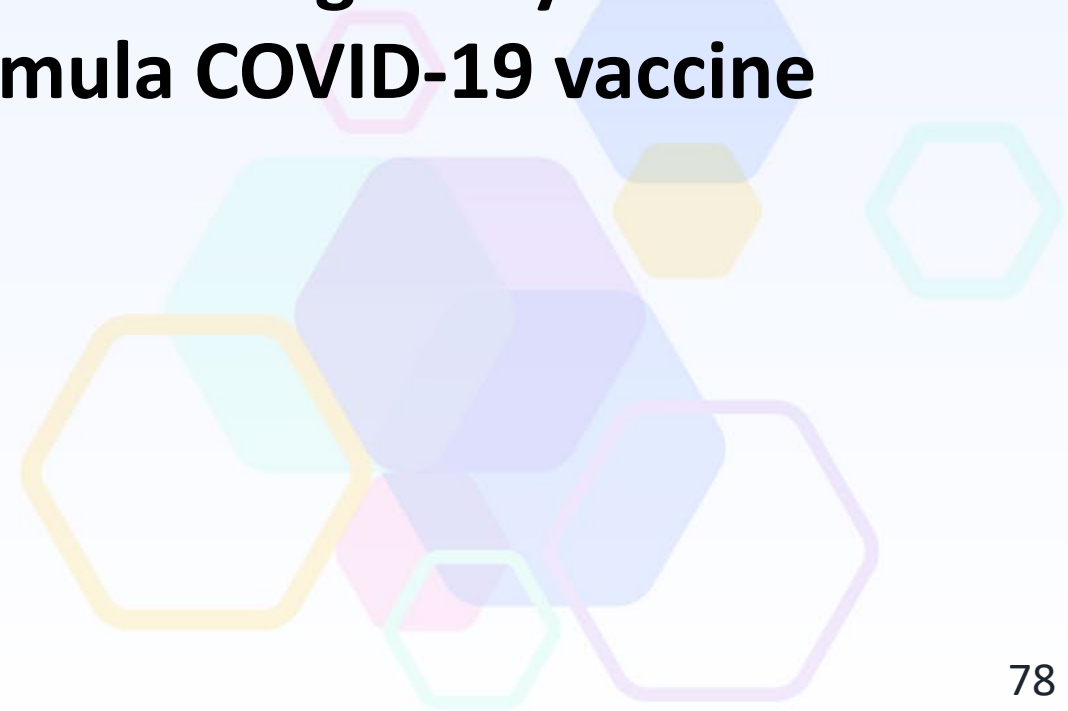
Evidence to Recommendations Framework

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 that persons ≥ 65 years of age may receive an additional dose of 2023-2024 Formula COVID-19 vaccine



Proposed Clinical Considerations

People ages 65 years and older may receive 1 additional dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech), informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Considerations for the additional dose may include a person’s risk for severe COVID-19 due to age and the presence of underlying medical conditions. The additional dose is administered at least 4 months following the previous dose of updated (2023–2024 Formula) COVID-19 vaccine.

Acknowledgements

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- Evelyn Twentyman
- Sierra Scarbrough
- Natalie Thornburg
- Jefferson Jones
- Aron Hall
- Dave Wentworth
- COVID-NET
- 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

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