Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations

Lakshmi Panagiotakopoulos, MD, MPH

Advisory Committee on Immunization Practices

April 15, 2025

Overview

- Current recommendations for 2024–2025 COVID-19 vaccines
- Policy options for 2025–2026 COVID-19 vaccine recommendations
- Supporting data and Work Group interpretations
- Discussion questions for committee

COVID-19 vaccine: ACIP Meeting Schedule

October 2024

- Additional dose of 2024-2025 COVID-19 vaccines in adults ages ≥65 years
- Additional dose(s) of 2024-2025 COVID-19 vaccines in moderately to severely immunocompromised persons ages ≥6 months

April 2025

- **Moderna mRNA-1283 COVID-19 vaccine**
- **Epidemiology and risk factors for COVID-19 hospitalizations**
- **Vaccine effectiveness update**
- **Work Group Considerations**
- **No vote scheduled**

June 2025 (proposed)

- **Vote on 2025–2026 COVID-19 vaccine recommendations (including additional dose recommendations)**

Review of 2024–2025 COVID-19 vaccine policy

Overview of the current COVID-19 vaccination schedule: *Routine vaccination*

- **Children ages 6 months–4 years**
  - Unvaccinated: Should receive a multidose initial series with a 2024–2025 mRNA vaccine
  - Previously completed an initial series: Should receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series
- **People ages 5–64 years:**
  - Should receive 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine*
- **People ages 65 years and older:**
  - Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)**

*People ages 12–64 years who are unvaccinated and receive the 2024–2025 Novavax COVID-19 vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine.
**People ages 65 years and older who are unvaccinated and receive Novavax COVID-19 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine followed by a third dose of any 2024–2025 COVID-19 vaccine dose 6 months after the second dose (minimum interval 2 months).
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#routine-vaccination-guidance

Overview of the current COVID-19 vaccination schedule: *Moderate or severe immunocompromise*

- **Unvaccinated:**
  - Should receive a multidose initial vaccination series with an age-appropriate 2024–2025 vaccine and receive 1 dose of 2024–2025 6 months after completing the initial series (minimum interval 2 months)
- **Previously completed an initial series:**
  - Should receive 2 doses of an age-appropriate 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)
- **May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under shared clinical decision-making** (minimum interval 2 months)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

Policy considerations for use of the 2025–2026 COVID-19 vaccine

Policy Options for 2025–2026 COVID-19 vaccines:
Multi-dose initial series

- **Currently a multi-dose initial series is recommended for people ages 6 months–4 years and people with immunocompromise**

  - **Option 1:** Maintain a universal vaccine policy for everyone ages ≥6 months that includes the multi-dose initial series

  - **Option 2:** Narrow current vaccine recommendations and only maintain this series for certain populations within these groups who we determine should be vaccinated

Policy Options for 2025–2026 COVID-19 vaccines:
Annual COVID-19 vaccine doses

- **Currently annual vaccines are recommended for everyone ages ≥6 months**

  - **Option 1:** Maintain a universal vaccine policy for everyone ages ≥6 months

  - **Option 2:** Risk-based recommendation only for groups at increased risk of severe COVID-19

  - **Option 3:** Combination of risk-based and universal vaccine recommendations (e.g., risked-based recommendation for ages 6 months-64 years and universal recommendations for ages ≥65 years.

Policy Options for 2025–2026 COVID-19 vaccines:
Semi-annual COVID-19 vaccine doses

- **Persons ages ≥65 years**
  - 2 doses per year for most; may be more if previously unvaccinated and receiving Novavax or immunocompromised
- **Persons ages ≥6 months who are moderately or severely immunocompromised**
  - Initial series if unvaccinated or post-immune ablative therapy
  - Initial series is followed by 2 doses per year
  - Additional doses can be administered under shared clinical decision-making

How to define who is at increased risk?

- **How much increased risk is needed to be included in a risk-based recommendation?**
- **Increased risk of severe outcomes**
  - Age
  - Underlying conditions
  - Pregnancy (also protects infants <6 months of age)
- **Risk of exposure**
  - Healthcare workers
  - People living in long-term care facilities and other congregate settings
  - Other groups at risk of increased exposure or transmission?

Higher Risk of Severe Illness of COVID-19 (conclusive)

- Asthma
- Cancer
  - Hematologic Malignancies
- Cerebrovascular disease
- Chronic kidney disease*
  - People receiving dialysis^
- Chronic lung diseases limited to:
  - Bronchiectasis
  - COPD (Chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - Pulmonary hypertension
- Chronic liver diseases limited to:
  - Cirrhosis
  - Non-alcoholic fatty liver disease
  - Alcoholic liver disease
  - Autoimmune hepatitis
- Cystic fibrosis
- Diabetes mellitus, type 1
- Diabetes mellitus, type 2*
- Disabilities‡,**, including Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
- HIV (Human immunodeficiency virus)
- Mental health conditions limited to:
  - Mood disorders, including depression
  - Schizophrenia spectrum disorders
- Neurologic conditions limited to dementia‡ and Parkinson's Disease
- Obesity (BMI $\geq$30 kg/m^2 or $\geq$95th percentile in children)
- Physical inactivity
- Pregnancy and recent pregnancy
- Primary immunodeficiencies
- Smoking, current and former
- Solid organ or blood stem cell transplantation
- Tuberculosis
- Use of corticosteroids or other immunosuppressive medications

* Indicates presence of evidence for pregnant and non-pregnant women
‡ Underlying conditions for which there is evidence in pediatric patients
^ Risk may be further increased for people receiving dialysis
** Attention-deficit/hyperactivity disorder (ADHD), Autism, Cerebral palsy, Charcot foot, Chromosomal disorders, Chromosome 17 and 19 deletion, Chromosome 18q deletion, Cognitive impairment, Congenital hydrocephalus, Congenital malformations, Deafness/hearing loss, Disability indicated by Barthel Index, Down syndrome, Fahr's syndrome, Fragile X syndrome, Gaucher disease, Hand and foot disorders, Learning disabilities, Leber's hereditary optic neuropathy (LHON) or Autosomal dominant optic atrophy (ADOA), Leigh syndrome, Limitations with self-care or activities of daily living, Maternal inherited diabetes and deafness (MIDD), Mitochondrial encephalopathy, lactic acidosis, and stroke-like episodes (MELAS) and risk markers, Mobility disability, Movement disorders, Multiple disability (referred to in research papers as "bedridden disability"), Multisystem disease, Myoclonic epilepsy with ragged red fibers (MERRF), Myotonic dystrophy, Neurodevelopmental disorders, Neuromuscular disorders, Neuromyelitis optica spectrum disorder (NMOSD), Neuropathy, ataxia, and retinitis pigmentosa (NARP), Perinatal spastic hemiparesis, Primary mitochondrial myopathy (PMM), Progressive supranuclear palsy, Senior-Loken syndrome, Severe and complex disability (referred to in research papers as "polyhandicap disability"), Spina bifida and other nervous system anomalies, Spinal cord injury, Tourette syndrome, Traumatic brain injury, Visual impairment/blindness, Wheelchair use

https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html

Higher Risk of Severe Illness of COVID-19 (conclusive)

- **Asthma**
- **Cancer**
  - Hematologic Malignancies
- **Cerebrovascular disease**
- **Chronic kidney disease***
  - People receiving dialysis^
- **Chronic lung diseases** limited to:
  - Bronchiectasis
  - COPD (Chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - Pulmonary hypertension
- **Chronic liver diseases** limited to:
  - **Cirrhosis**
  - **Non-alcoholic fatty liver disease**
  - Alcoholic liver disease
  - Autoimmune hepatitis
- **Cystic fibrosis**
- **Diabetes mellitus, type 1**
- **Diabetes mellitus, type 2***
- Disabilities‡,**, including Down syndrome
- **Heart conditions** (such as heart failure, coronary artery disease, or cardiomyopathies)
- **HIV (Human immunodeficiency virus)**
- **Mental health conditions** limited to:
  - **Mood disorders,** including **depression**
  - **Schizophrenia** spectrum disorders
- **Neurologic conditions limited to dementia‡** and Parkinson's Disease
- **Obesity** (BMI ≥30 kg/m^2 or ≥95th percentile in children)
- Physical inactivity
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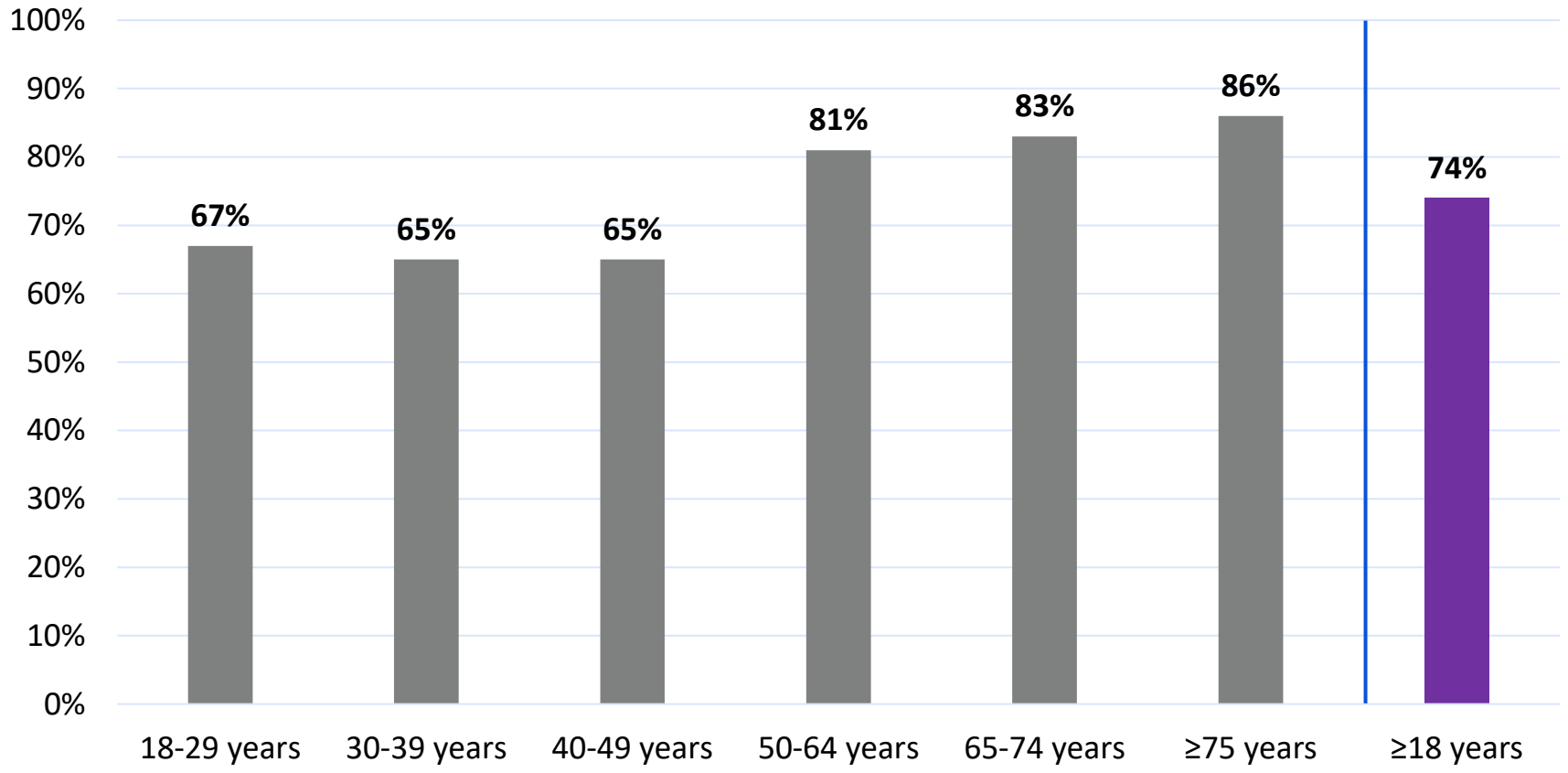
Bolded conditions were included in analysis on prevalence of risk conditions by the Center for Forecasting Analytics (unpublished data); those highlighted by the red boxes were not included
https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html

Estimates of adults in the United States with at least 1 condition that puts them at higher risk of severe illness from COVID-19, by age group, October 2022–September 2023



Unpublished results from September 2024 analysis of medical claims data, consumer data, Behavioral Risk Factors Surveillance System, and/or National Health Interview Survey to enumerate the US population with conditions that put them at increased risk of severe illness from COVID-19 using multilevel regression modeling, CDC Center for Forecasting and Outbreak Analytics

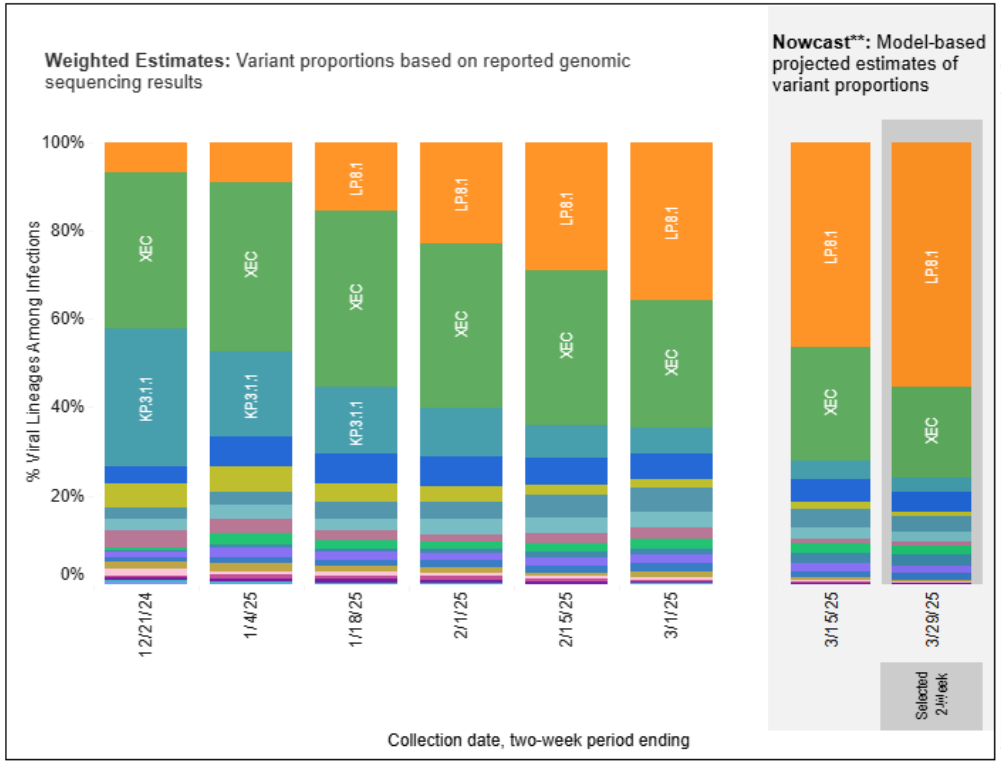
Summary of supporting evidence

COVID-19 Epidemiology

Weighted and Nowcast SARS-CoV-2 estimates in the United States for 2-week periods, December 8, 2024–March 29, 2025

Weighted and Nowcast Estimates in United States for 2-Week Periods in 12/8/2024 – 3/29/2025

Hover over (or tap in mobile) **any lineage of interest** to see the amount of uncertainty in that lineage's estimate.



Nowcast Estimates in United States for 3/16/2025 – 3/29/2025

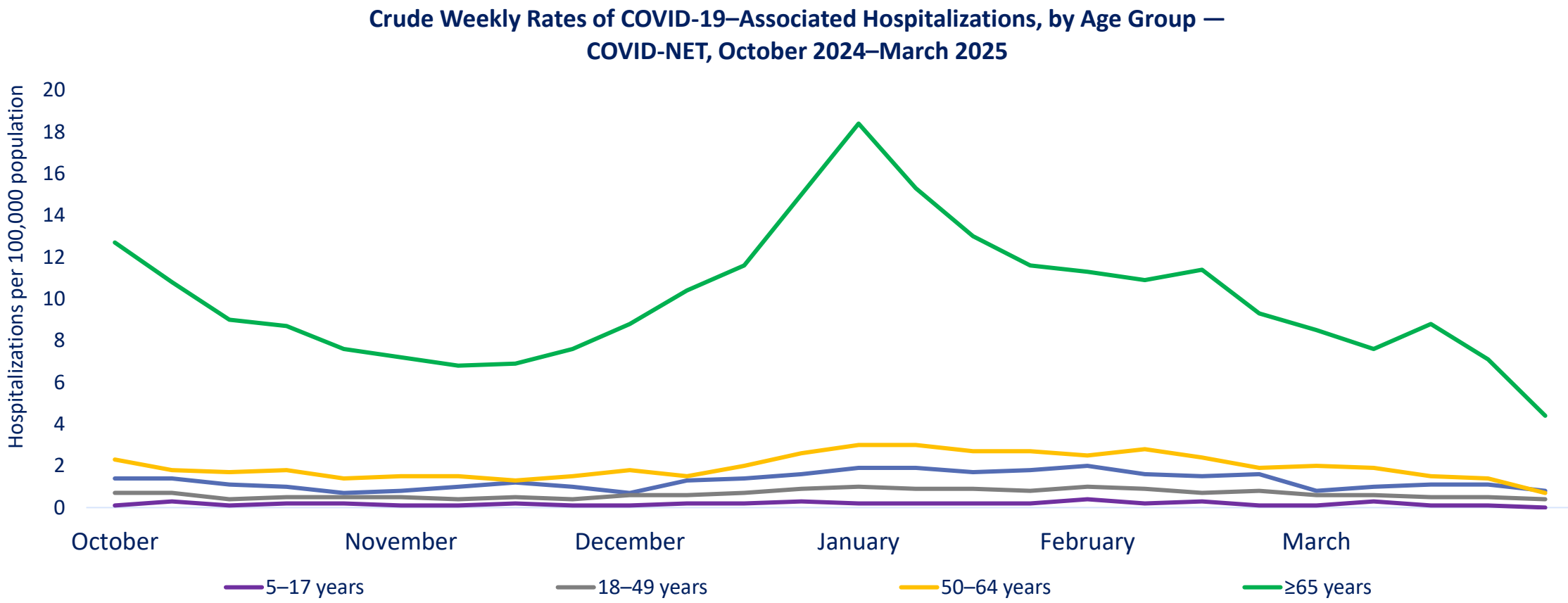
USA

WHO label	Lineage #	%Total	95%PI
Omicron	LP.8.1	55%	48–62%
	XEC	21%	17–24%
	MC.10.1	4%	1–11%
	LF.7	4%	2–6%
	KP.3.1.1	3%	2–6%
	MC.28.1	3%	1–6%
	LB.1.3.1	2%	1–4%
	XEC.4	2%	1–3%
	XEQ	2%	1–3%
	MC.19	1%	1–3%
	MC.1	1%	1–2%
	KP.3	1%	0–2%
	XEK	0%	0–1%
	JN.1.16	0%	0–1%
	JN.1	0%	NA
	KP.1.1.3	0%	NA
	KP.2.3	0%	NA

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed. While all lineages are tracke by CDC, those named lineages not enumerated in this graphic are aggregated with their parent lineages, based on Pango lineage definitions, described in more detail here: https://web.archive.org/web/20240116214031/https://www.pango.network/the-pango-nomenclature-system/statement-of-nomenclature-rules.

These data include Nowcast estimates, which are modeled predictions that may differ from weighted estimates generated at later dates
https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed April 7, 2025

Weekly rates of COVID-19–associated hospitalizations in the United States by age group, October 2024–March 2025

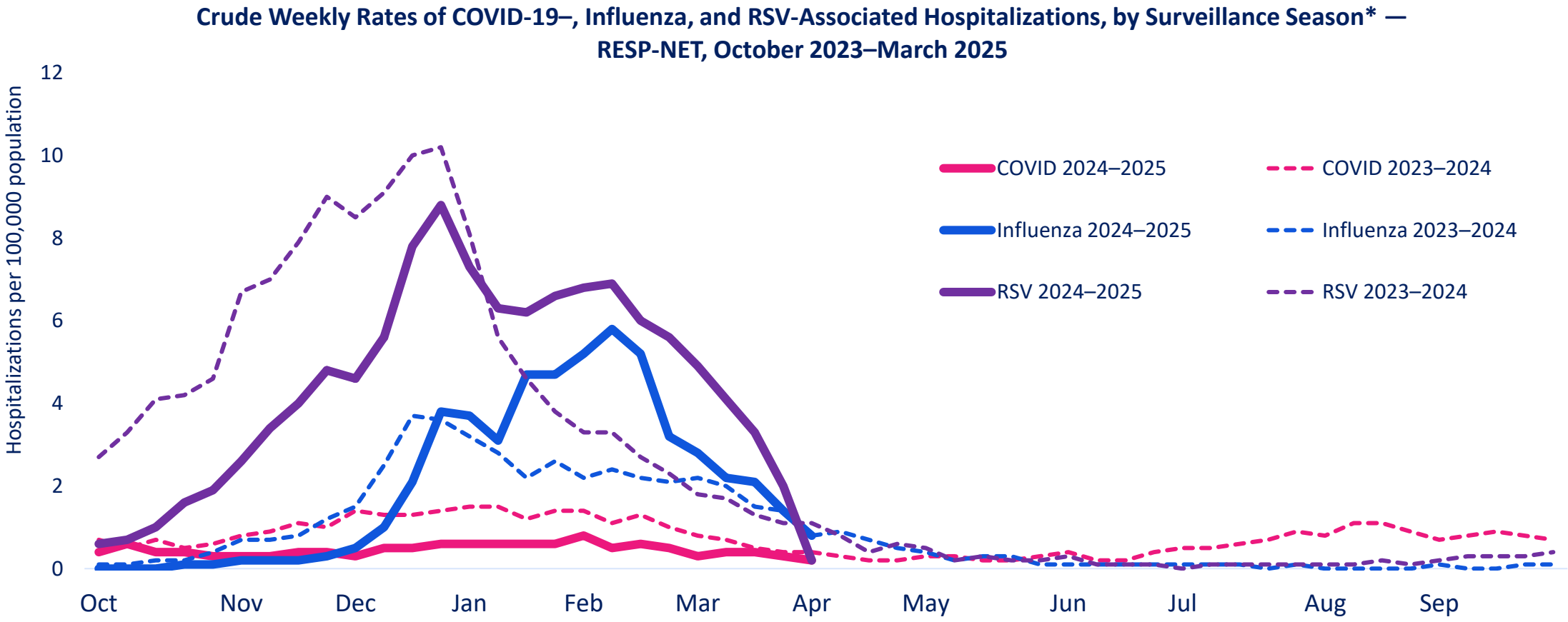


Rates for all three pathogens (COVID-19, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed.

Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

Data source: https://www.cdc.gov/resp-net/dashboard/ Accessed April 7, 2025

Weekly rates of respiratory virus-associated hospitalizations in the United States among children ages 0–17 years, 2023–2025



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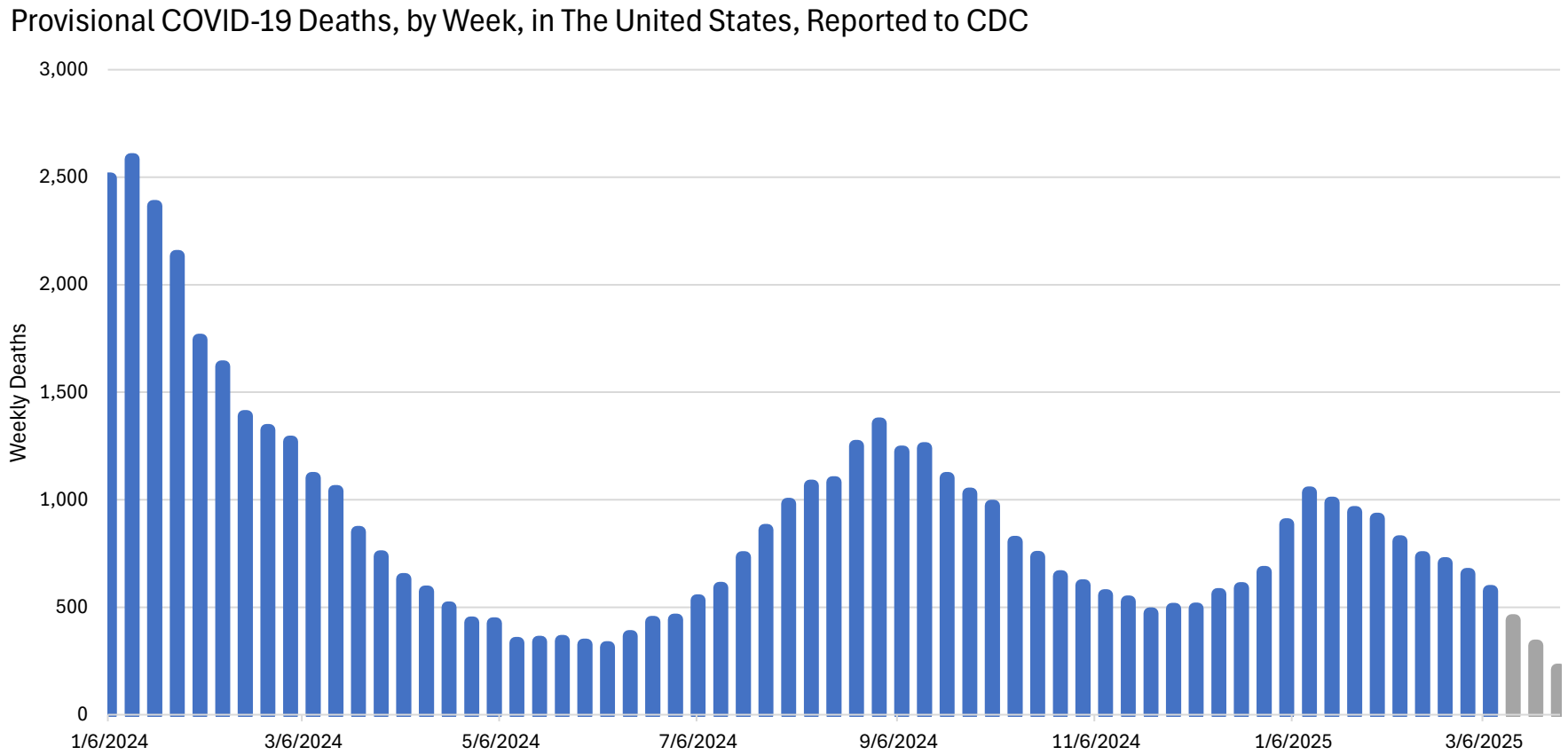
Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

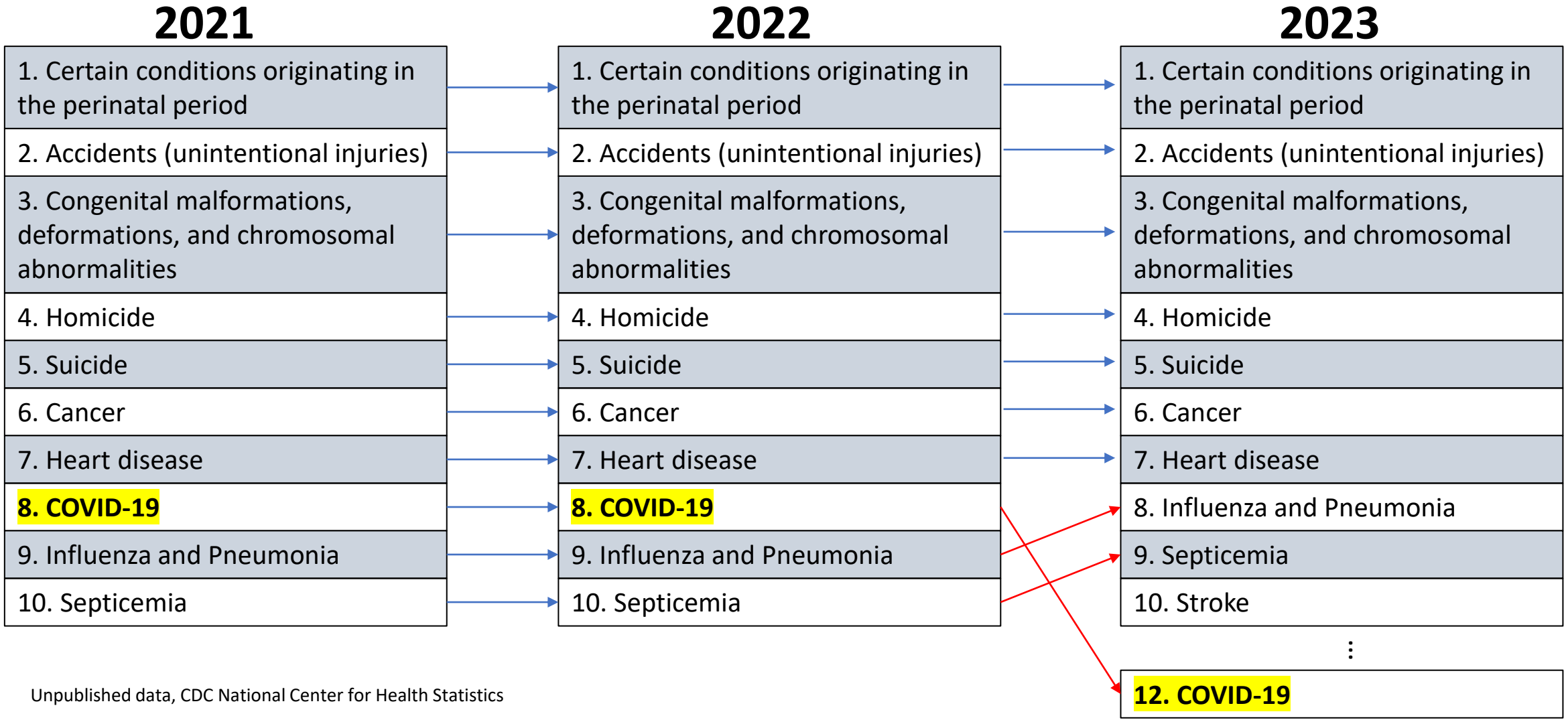
Data source: https://www.cdc.gov/resp-net/dashboard/ accessed April 7, 2025

Weekly number of COVID-19 deaths reported to CDC, United States, January 1, 2024 – March 29, 2025



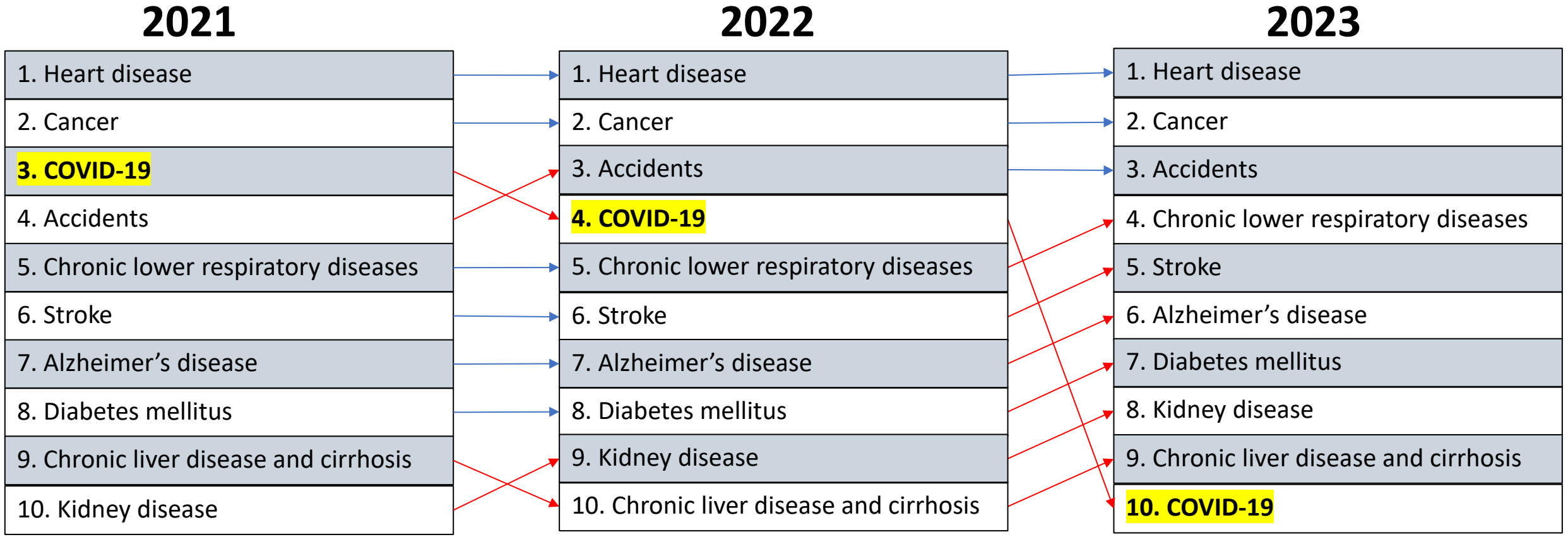
The most recent 3 weeks of mortality counts are shaded grey because NVSS reporting is s <95% during this period.
Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD–10 code U07.1, on the death certificate. Death data are displayed by date of death (event). Data include underlying and contributing causes of death.
CDC COVID Data Tracker. National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS). https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00 . Accessed April 7, 2025

Top 10 leading causes of death in the United States, children and adolescents 0–17 years



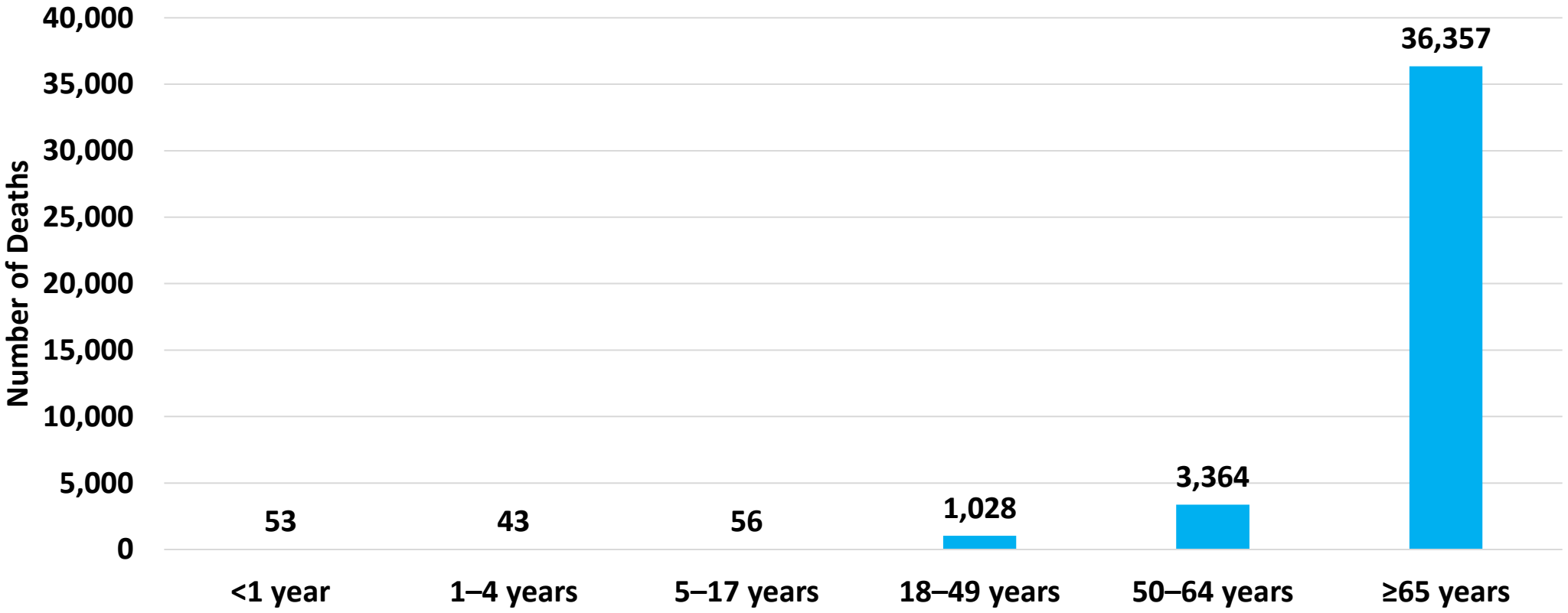
Unpublished data, CDC National Center for Health Statistics

Top 10 leading causes of death in the United States, adults ages ≥18 years



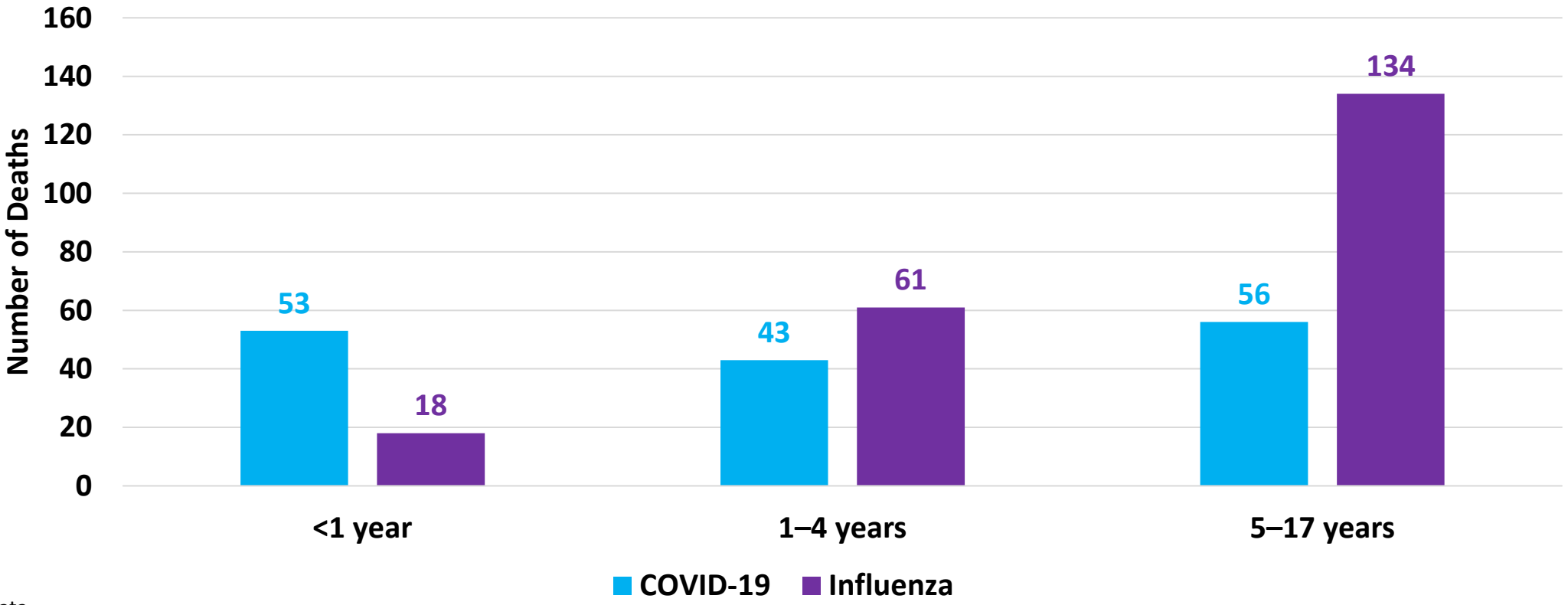
Influenza and pneumonia was ranked 9th pre-pandemic in 2019; ranked 13th in 2023
Unpublished data, CDC National Center for Health Statistics

Total number of COVID-19 deaths,[1,2] September 2023–August 2024, by age group, United States



1. Provisional data
2. Underlying cause of death 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 Underlying Cause of Death Files, 2018-2023, and from provisional data for 2024, 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. http://wonder.cdc.gov/mcd-icd10-provisional.html, accessed January 16, 2025

Total number of COVID-19 and Influenza deaths[1,2], among ages 0–17 years, September 2023–August 2024, United States



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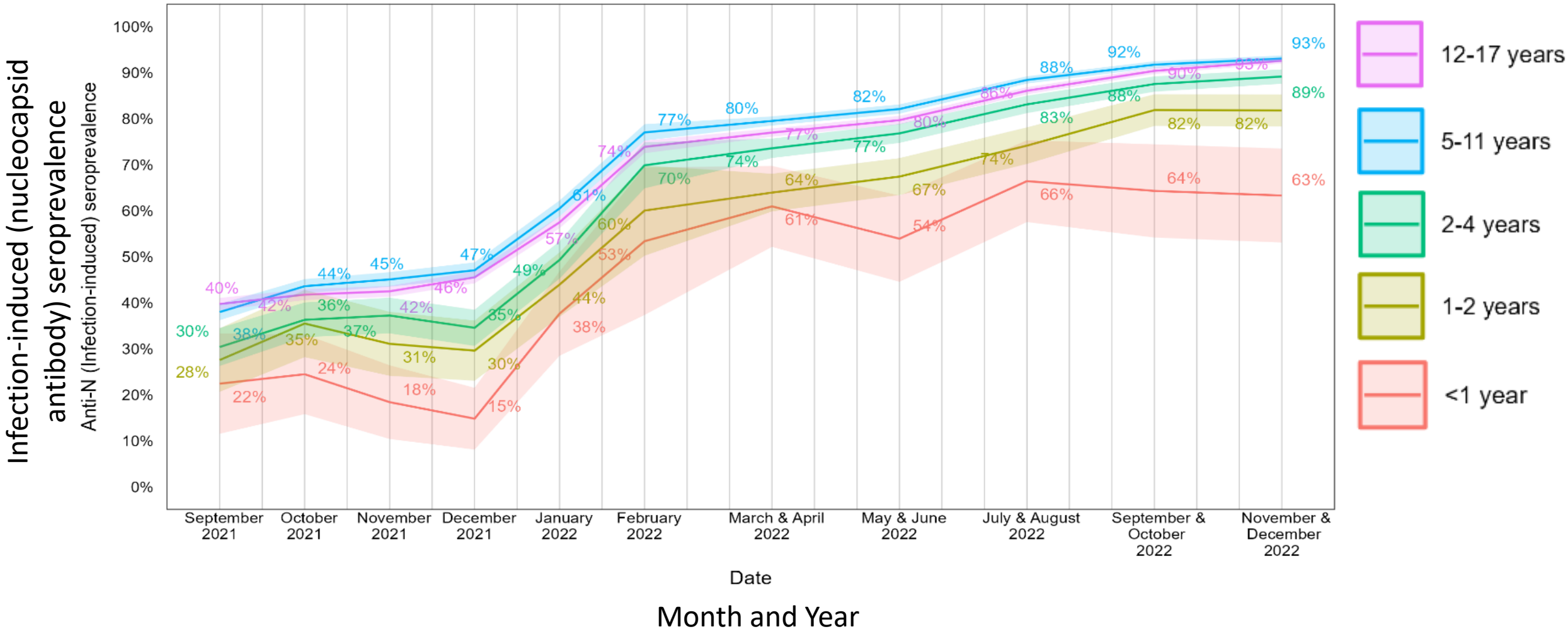
Note: Estimates of pediatric influenza deaths reported to CDC can be found here: https://www.cdc.gov/flu/weekly/index.htm. Estimates will vary due to differences in reporting methods and timeframes used.

COVID-19—associated changes from 2023–2024 to 2024–2025

	2023–2024	2024–2025	Difference
Routine vaccine recommendation	6 months and older 65 and older: 2 doses	6 months and older 65 and older: 2 doses	No change
Vaccine coverage <18 years[1]	13.8% (13.4–14.3) (3/23/2024)	12.8% (12.2–13.4) (3/22/2025)	Similar
Vaccine coverage ≥18 years[2]	21.3% (21.0–21.5) (3/23/2024)	23.1% (22.5–23.7) (3/22/2025)	Similar
Vaccine coverage ≥65 years[2]	37.5% (36.7–38.3) (3/23/2024)	44.0% (42.5–45.4) (3/22/2025)	***Increase***
Vaccine effectiveness against hospitalization, immunocompetent adults ≥65 years	VISION: 42% (37–47)[3] IVY: 35% (20–47)[3]	VISION: 45% (36–53)[4] IVY: 46% (26–60)[4]	Similar
Cumulative hospitalization rates (week 13)[5]	125.6/100,000	62.9/100,000	***Decrease***

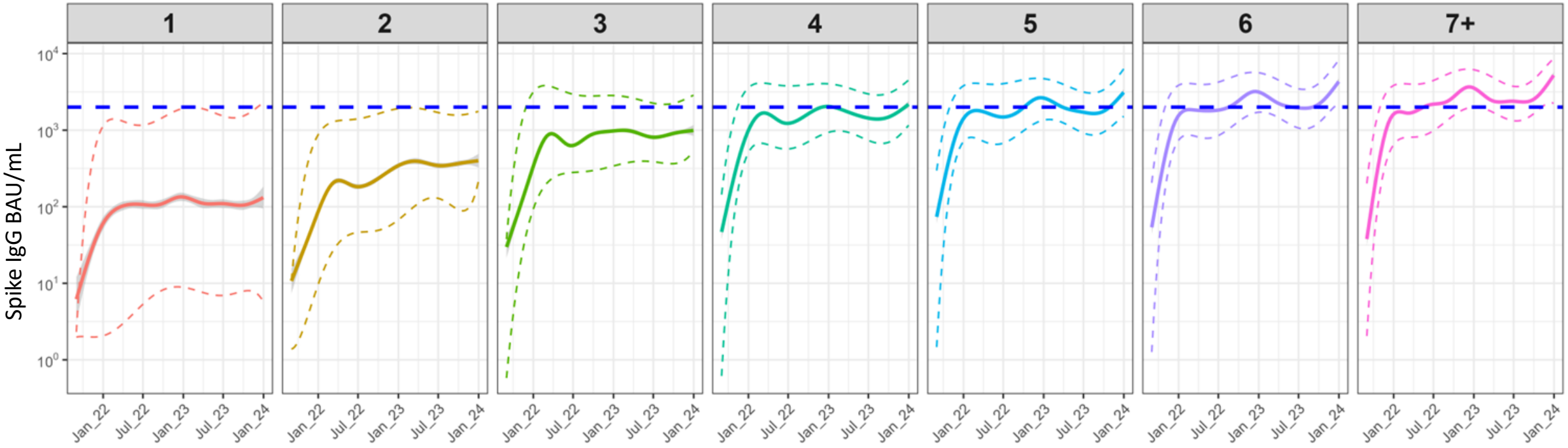
1 https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html, accessed April 7, 2025
2 https://www.cdc.gov/covidvaxview/weekly-dashboard/adult-vaccination-coverage.html, accessed April 7, 2025
3 https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/03-COVID-Link-Gelles-508.pdf; median (IQR) days since dose: VISION: 84 (46–127) IVY: 81 (43–121)
4 Link-Gelles R, Chickery S, Webber A, et al. Interim Estimates of 2024–2025 COVID-19 Vaccine Effectiveness Among Adults Aged ≥18 Years — VISION and IVY Networks, September 2024–January 2025. MMWR Morb Mortal Wkly Rep 2025;74:73–82. Median (IQR) days since dose– VISION: 53 (30–77) IVY: 60 (31–85)
5 https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network, accessed April 7, 2025

Infection-induced SARS-CoV-2 seroprevalence among U.S. children — September 2021 – December 2022



Shaded ranges depict 95% confidence intervals for the estimated seroprevalence shown by the dark line in the corresponding color.
Source: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence
Accessed: March 20, 2025

Population SARS-CoV-2 spike antibody over time by the cumulative number of combined infections and vaccinations - U.S. blood donors ages ≥16 years, September 2021-December 2023



Solid lines represent mean anti-spike IgG levels; dotted lines represent model based 25th-75th% percentiles

Higher number of cumulative SARS-CoV-2 infections and COVID-19 vaccinations leads to higher antibody levels, but with smaller incremental increases in antibodies with each exposure

Source: https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022, CDC unpublished data

Long COVID is a significant public health threat

National surveys in 2023 estimated approximately 9.2 million adults and 0.3 million children in the U.S. had Long COVID.

Among adults aged ≥18 years, **3.6% reported Long COVID symptoms,** and **8.4% reported ever having Long COVID**[1]

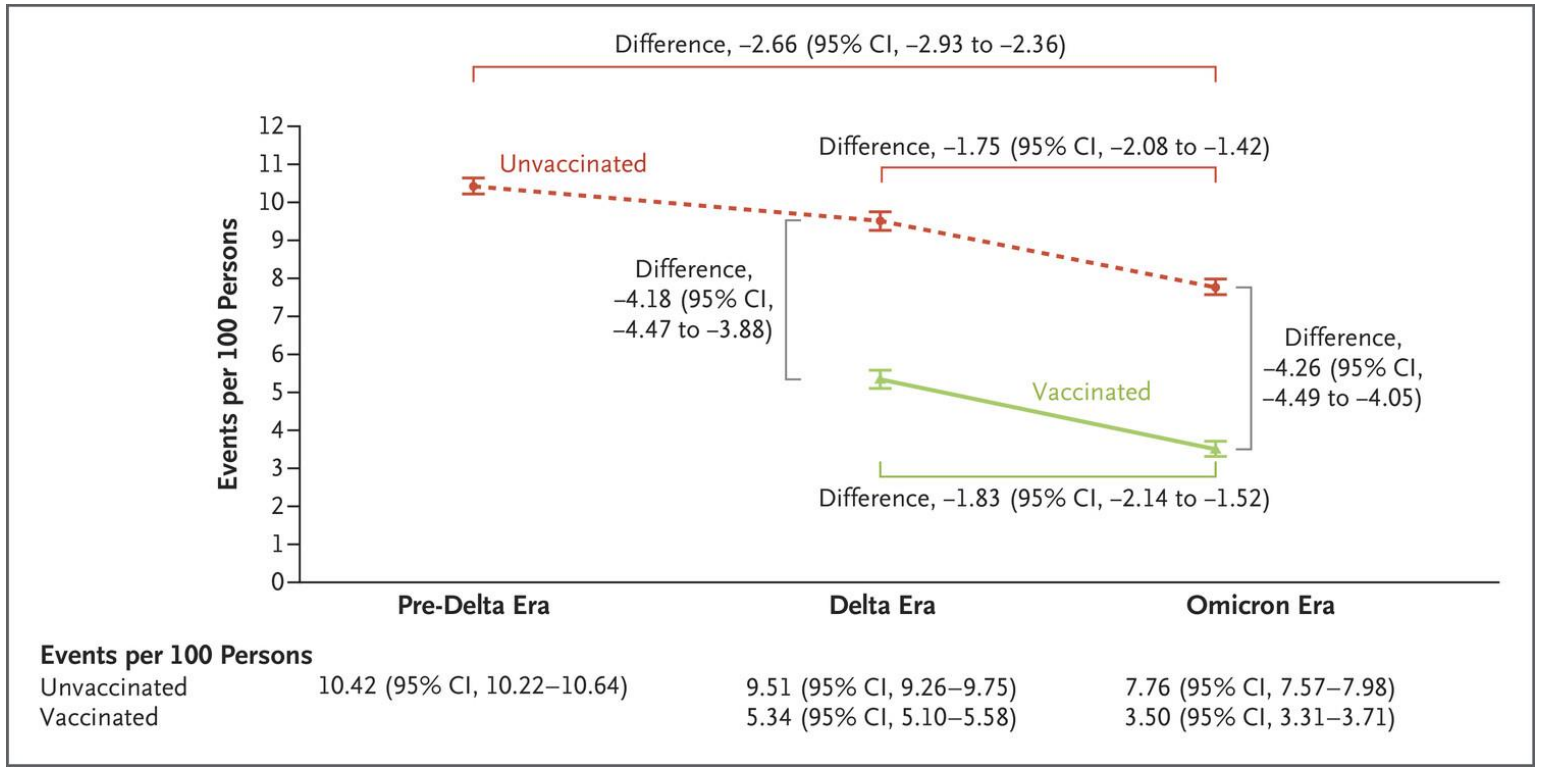
Among children aged 0-17 years, **0.4% reported Long COVID symptoms,** and **1.4% reported ever having Long COVID**[2]

More than 3 in 5 adults with Long COVID report activity limitations[1]

Almost 4 in 5 children with Long COVID report activity limitations[2]

1. Vahratian A, Saydah S, Bertolli J, Unger ER, Gregory CO. Prevalence of Post–COVID-19 Condition and Activity-Limiting Post–COVID-19 Condition Among Adults. *JAMA Netw Open.* 2024;7(12):e2451151.
2. Ford ND, Vahratian A, Pratt CQ, Yousaf AR, Gregory CO, Saydah S. Long COVID Prevalence and Associated Activity Limitation in US Children. *JAMA Pediatr.* Published online February 03, 2025.

Incidence of Long COVID has decreased, but still occurs



- **Vaccinated persons had a lower cumulative incidence of Long COVID at 1 year following SARS-CoV-2 infection than unvaccinated persons**

Health records from Department of Veterans Affairs included 441,583 veterans with SARS-CoV-2 infection between March 1, 2020, and January 31, 2022, and 4,748,504 noninfected contemporaneous controls. Cumulative incidence of Long COVID (defined as incidence of newly diagnosed symptoms and conditions not present prior to index date) measured at 1 year after SARS-CoV-2 infection during the pre-Delta, Delta, and Omicron eras of the Covid-19 pandemic.

Xie Y, Choi T, Al-Aly Z. Postacute Sequelae of SARS-CoV-2 Infection in the Pre-Delta, Delta, and Omicron Eras. N Engl J Med. 2024 Aug 8;391(6):515-525.

COVID-19 mRNA vaccination associated with reduced occurrence of Long COVID following COVID-19: June 2021-September 2022

Among children 5 – 17 years:

Completion of the primary vaccine series prior to infection associated with **reduced likelihood** of Long COVID symptoms[1]

- **57% for 1 or more symptoms**
- **73% for 2 or more symptoms**
- **72% for respiratory symptoms**

Among adults:

3 doses of original monovalent vaccine prior to infection associated with **reduced likelihood** of Long COVID symptoms[2]

- **63% for gastrointestinal symptoms**
- **44% for neurological symptoms**
- **52% for other non-specific symptoms**

1. Yousaf AR, Mak J, Gwynn L, et al. COVID-19 Vaccination and Odds of Post–COVID-19 Condition Symptoms in Children Aged 5 to 17 Years. *JAMA Netw Open.* 2025;8(2):e2459672.
2. Mak J, Khan S, Britton A et al. Association of Messenger RNA Coronavirus Disease 2019 (COVID-19) Vaccination and Reductions in Post COVID Conditions Following Severe Acute Respiratory Syndrome Coronavirus 2 Infection in a US Prospective Cohort of Essential Workers, The Journal of Infectious Diseases, Volume 231, Issue 3, 15 March 2025, Pages 665–676

Multisystem Inflammatory Syndrome in Children (MIS-C) U.S. Incidence Over Time

- US incidence of MIS-C by SARS-CoV-2 variant-predominant periods was previously published[1], updated data shown below
  - Defined using surveillance data and allowing for 2 weeks to MIS-C onset from when a variant exceeded 50% circulating lineages

Variant predominant period	Dates	Number of MIS-C cases	Incidence per 1,000,000 (95% CI) person-years	Median age (IQR), years
Pre-Delta	Oct 15, 2020–Apr 5, 2021	3,287	6.80 (6.57–7.03)	9.2 (5.4–13.1)
Delta	Jul 10–Dec 24, 2021	2,305	4.91 (4.71–5.11)	9.1 (5.5–12.3)
Omicron BA.1/BA 1.1	Jan 1–Apr 8, 2022	1,148	4.21 (3.97–4.46)	7.5 (4.1–11.5)
Omicron BA.2/BA.4/BA.5	Apr 9–Dec 31, 2022	428	0.57 (0.52–0.63)	5.4 (2.9–9.7)
Omicron XBB.1.5	Jan 1–Dec 31, 2023	141	0.14 (0.12–0.16)	6.9 (3.7–11.5)
Omicron JN.1/others	Jan 1-Dec 31, 2024	79	0.08 (0.06 - 0.10)	9.1 (4.7-14.3)

- Similarly decreased incidence was observed in other countries[2-4]

1. Yousaf AR, et al, *MMWR* 2023
2. Shingleton J et al, *Journal of Infection*, 2022.
3. Cohen JM, et al. *Clin Infect Dis*. 2023
4. Whittaker R et al. *Pediatrics.* 2022

COVID-19 Vaccination Status of 2023 and 2024 U.S. Multisystem Inflammatory Syndrome in Children (MIS-C) Cases

	2023 Illness Onset N=141 (%)	2024 Illness Onset N=79 (%)
Vaccine age-eligible[1] at time of MIS-C onset	134 (95)	78 (99)
No vaccination	108/134 (81)	58/78 (74)
Vaccinated (at least one dose received)	26/134 (19)	20/78 (26)
Last vaccine dose >12 months before MIS-C onset	17/26 (65)	20/20 (100)

[1]10 months of age at onset considered the minimum age by which a child could plausibly have completed an mRNA primary vaccination series, with 6 months being the earliest possible age at first dose and ≥12 weeks from first dose required to complete a 3-dose primary series, and 4 weeks between time since last dose and hospitalization

- **Although 95% of children with MIS-C in 2023 and 99% in 2024 were eligible to receive a COVID-19 vaccine ≥16 weeks before their MIS-C illness, only 19% in 2023 and 26% in 2024 of eligible children received any vaccine dose**
- **Of the 25 vaccinated children in 2023 with information on timing, 65% in 2023 received their last vaccine dose more than 12 months prior to MIS-C onset**
- **All vaccinated children in 2024 received their last vaccine dose > 12 months prior to MIS-C onset**

Yousaf AR et al, MMWR 2023 and unpublished data

COVID-19 Vaccine and Myocarditis

COVID-19 vaccine prescribing information or fact sheet warnings and precautions about myocarditis and pericarditis

Manufacturer	Precaution
Pfizer	Post marketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, the observed risk is highest in males 12 through 17 years of age.
Moderna	Post marketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For SPIKEVAX, the observed risk is highest in males 18 years through 24 years of age.
Novavax	Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted.

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines-2024-2025

CDC's Interim Clinical Considerations guidance on myocarditis and pericarditis

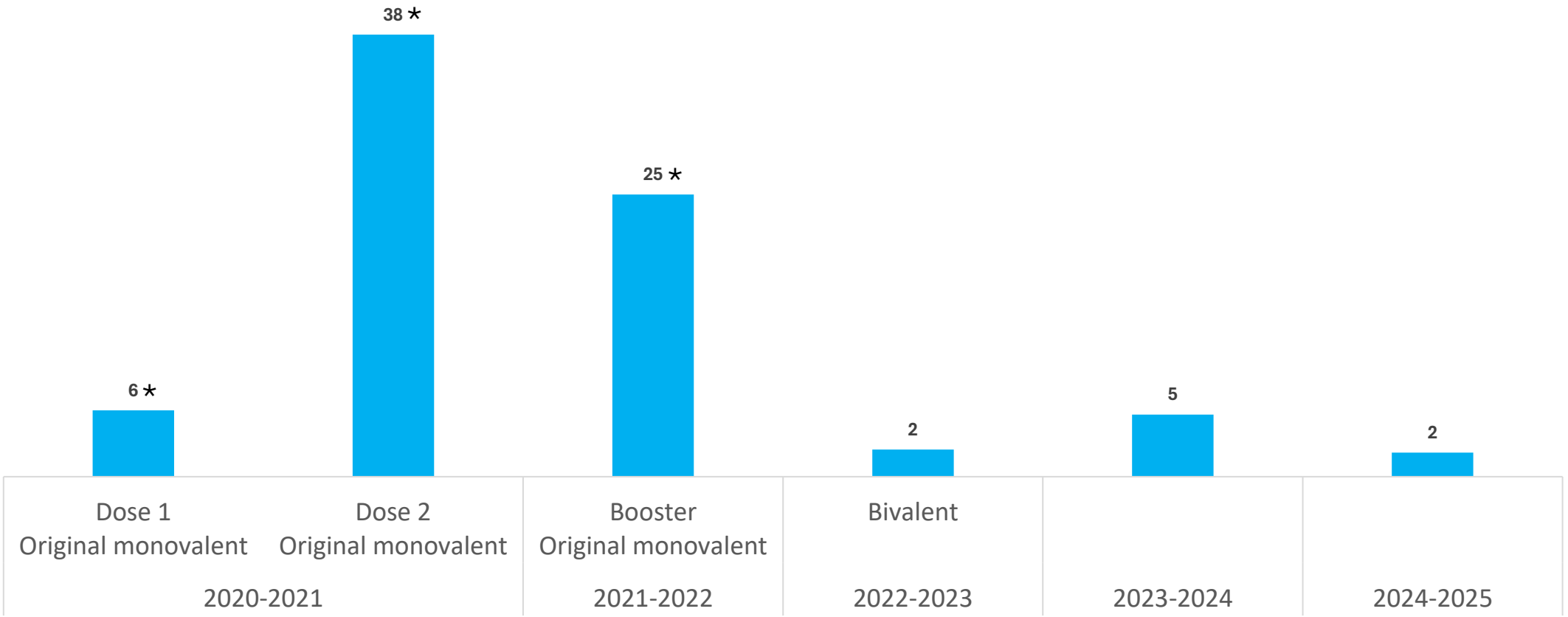
- **Extended intervals for multidose series**
  - An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

- **Myocarditis within 3 weeks of COVID-19 vaccines**
  - Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis

Myocarditis following mRNA COVID-19 vaccination among people ages 12–39 years in the Vaccine Safety Datalink

Incidence of myocarditis within 7 days of vaccination per million mRNA vaccine doses administered



*Statistically significant increased rate ratio in vaccinated concurrent comparator analysis
Source: CDC Immunization Safety Office, unpublished data

Myocarditis/pericarditis concurrent comparator analysis in Vaccine Safety Datalink (VSD) after COVID-19 vaccine doses among people ages 12-39 years, 2024-2025

Vaccine	Doses	Cases in Risk Interval (Days 1-21)	Cases in Comparison Interval (Days 22-42)	Adjusted Rate Ratio[1] (95% Confidence Interval)
Pfizer	530,095	5	5	0.61 (0.11 – 2.88)
Moderna	35,194	0	0	n/a
Novavax	1,576	0	0	n/a

- **The VSD has not detected a statistical signal for myocarditis/pericarditis following COVID-19 vaccines for the 2024-2025 season to date**

[1] Adjusted for outcome calendar date, age group, sex, race/ethnicity, VSD site
Source: CDC Immunization Safety Office, unpublished data through March 22, 2025

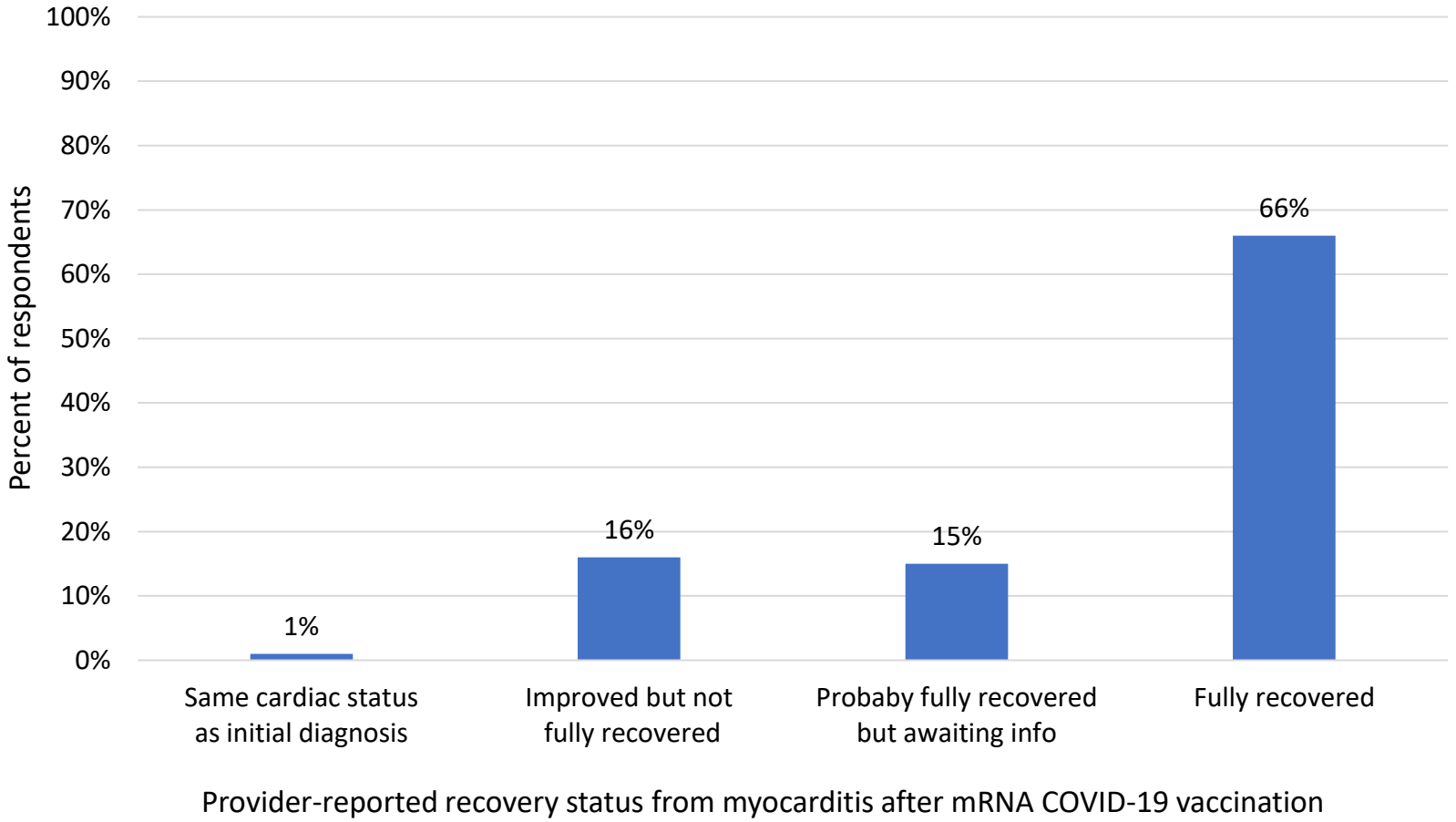
Vaccine Adverse Event Reporting System (VAERS) reports of myocarditis within 7 days of COVID-19 vaccination among people ages 12-39 years, 2024-2025

Age group (years)	Verified cases	Reporting rate per million doses
12-17	3	0.74
18-29	0	0
30-39	1	0.14

- **The reporting rates are similar to the expected background rates of <2 cases per million doses**

Source: CDC Immunization Safety Office, unpublished data through March 22, 2025

MOVING Study: Outcomes after myocarditis following COVID-19 vaccine: Cardiologist/healthcare provider assessment of recovery in persons ages 12–29 years at least 90 days since onset of myocarditis after COVID-19 vaccination, 2021-2022



- **81% (320/393) of patients were considered fully or probably recovered by their cardiologist or other healthcare provider**

Kracalik I, Oster ME, Broder KR et al. Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child & Adolescent Health,* 2022.

MOVING: Myocarditis Outcomes after COVID-19 Vaccine INvestiGation

MOVING* study: Outcomes after myocarditis following COVID-19 vaccine: Patient-reported assessment of recovery in persons ages 12–29 years at least 90 days since onset of myocarditis after COVID-19 vaccination, 2021-2022

	Patients fully or probably fully recovered (n=320)	Patients not recovered (n=65)	All patients (n=519)	p value
Patient-reported symptoms in the patient survey	n=195§	n=28§	n=357	..
At least one symptom	94 (48%)	18 (64%)	178 (50%)	0·16
Chest pain or discomfort	55 (28%)	13 (46%)	113 (32%)	0·082
Chest pain or discomfort while resting	45 (23%)	11 (39%)	92 (26%)	0·011
Fatigue	40 (21%)	12 (43%)	89 (25%)	0·018
Fatigue while resting	28 (14%)	10 (36%)	63 (18%)	0·012
Shortness of breath	38 (19%)	9 (32%)	80 (22%)	0·28
Shortness of breath while resting	15 (8%)	4 (14%)	38 (11%)	0·42
Heart palpitations	36 (18%)	6 (21%)	77 (22%)	0·71
Heart palpitations while resting	28 (14%)	5 (18%)	59 (17%)	0·84

- **50% (178/357) of patients self-report at least 1 lingering symptom at 3 months**

*MOVING: Myocarditis Outcomes after COVID-19 Vaccine INvestiGation

Kracalik I, Oster ME, Broder KR et al. Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child & Adolescent Health,* 2022.

Comparison of myocarditis attributed to COVID-19 mRNA vaccination, SARS-CoV-2 infection or conventional etiologies, 2020-2022

Table 3. Associations Between Clinical Outcomes and Myocarditis Groups Over 18 Months

Outcome	Postvaccine myocarditis (n = 558)		Post-COVID-19 myocarditis (n = 298)		Conventional myocarditis (n = 3779)	
	No. of events (%)	Weighted hazard ratio[a]	No. of events (%)	Weighted hazard ratio[a]	No. of events (%)	Weighted hazard ratio[a]
Rehospitalization for myopericarditis	18 (3.2)	0.75 (0.40-1.42)	12 (4.0)	1.07 (0.53-2.13)	220 (5.8)	1
Cardiovascular event (excluding myopericarditis)	15 (2.7)	0.54 (0.27-1.05)	22 (7.4)	1.01 (0.62-1.64)	277 (7.3)	1
Heart failure, heart rhythm and conduction disorders, cardiomyopathy[b]	6 (1.1)	0.53 (0.07-4.28)	11 (3.7)	1.23 (0.58-2.63)	132 (3.5)	1
Hospitalization for any cause	68 (12.2)	0.69 (0.50-0.94)	63 (21.1)	1.04 (0.73-1.48)	739 (19.6)	1
Death from any cause	1 (0.2)		4 (1.3)		49 (1.3)	1
Composite outcome 1[c]	32 (5.7)	0.55 (0.36-0.86)	36 (12.1)	1.04 (0.70-1.52)	497 (13.2)	1
Composite outcome 2[c]	75 (13.4)	0.64 (0.48-0.85)	76 (25.5)	1.03 (0.75-1.40)	874 (23.1)	1

Composite outcome 1: rehospitalization for myopericarditis, cardiovascular event, or death from any cause.
Composite outcome 2: rehospitalization for myopericarditis, cardiovascular event, hospitalization for any cause (>1 night stay), or death from any cause.

Semenzato L, Le Vu S, Botton J et al. Long-term prognosis of patients with myocarditis attributed to COVID-19 mRNA vaccination, SARS-CoV-2 infection, or conventional etiologies. *JAMA*. 2024. https://jamanetwork.com/journals/jama/fullarticle/2822933

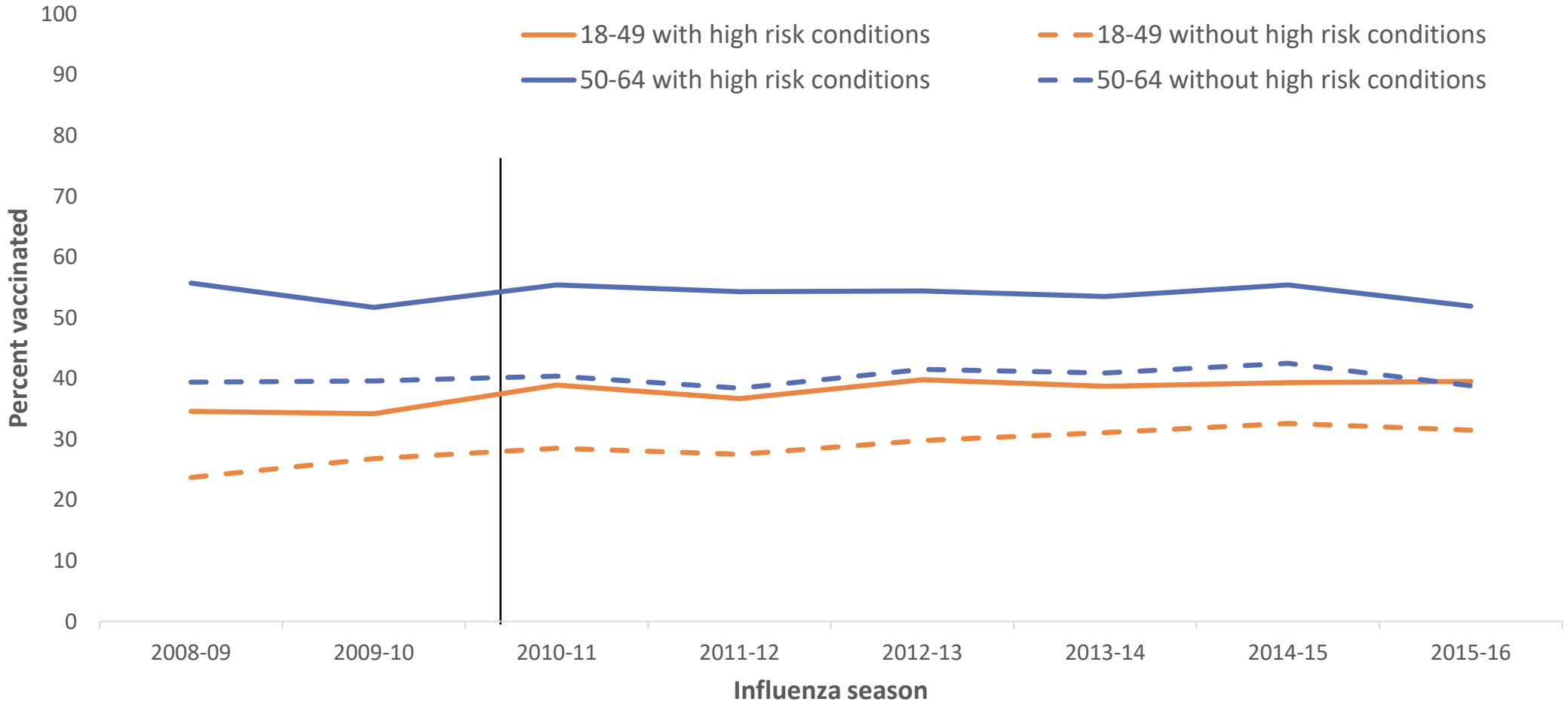
Summary: myocarditis after COVID-19 vaccine

- An increased risk of myocarditis following COVID-19 vaccines was observed during 2020-2022 following the primary series and first booster doses
- No increased risk was observed in VSD and VAERS during the 2022-2023 and 2023-2024 seasons or the 2024-25 season to date
- Acute clinical picture following myocarditis after COVID-19 vaccine tends to resolve quickly
- Post-COVID-19 vaccine myocarditis associated with less severe cardiovascular events than post-COVID-19 myocarditis and conventional myocarditis

VSD: Vaccine Safety Datalink | VAERS: Vaccine Adverse Event Reporting System

Risk-based v. universal vaccine coverage

Influenza vaccination coverage among adults 18-64 years with and without high-risk medical conditions, 2008–09 through 2015–16 influenza seasons, Behavioral Risk Factor Surveillance System



Vertical line denotes timing of universal influenza vaccination recommendation

Selected high risk conditions include asthma, diabetes or heart disease (before the 2013-14 season) or asthma, diabetes, heart disease, chronic obstructive pulmonary disease or cancers other than skin cancer (2013-14 season through present)

Source: CDC Immunization Services Division, unpublished

Vaccination coverage: risk-based vs. universal recommendations

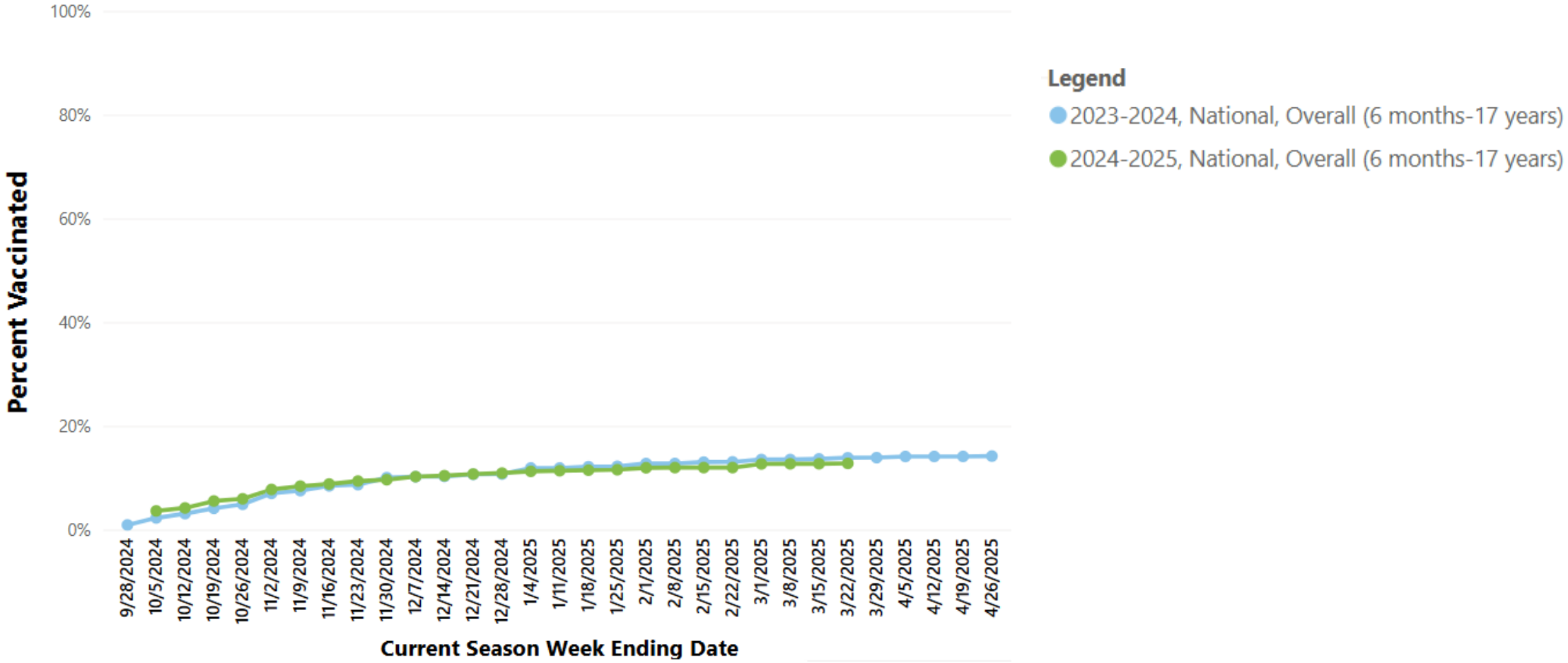
- **Influenza vaccination coverage among adults with high-risk conditions increased slightly after the universal recommendation in the 2010-11 season, but it was already trending upward and plateaued shortly after the change in recommendation.**
- **Hepatitis B vaccination coverage among adults with risk factors remained below pre-pandemic coverage after the universal recommendation in 2022.**
- **Coverage among adults universally recommended for zoster vaccination was approaching pneumococcal vaccination coverage among high-risk adults by 2023, despite longstanding pneumococcal vaccination recommendations for high-risk adults.**
- **It is unclear how a change from a universal to risk-based recommendations may impact COVID-19 vaccine coverage**

Source: CDC Immunization Services Division, unpublished data

Parental vaccine confidence

COVID-19 vaccination coverage among children 6 months–17 years, United States, 2023-2024 through 2024-2025

- As of March 22, 2025, 12.8% of children 6 months-17 years reported having received the 2024–25 COVID-19 vaccine.

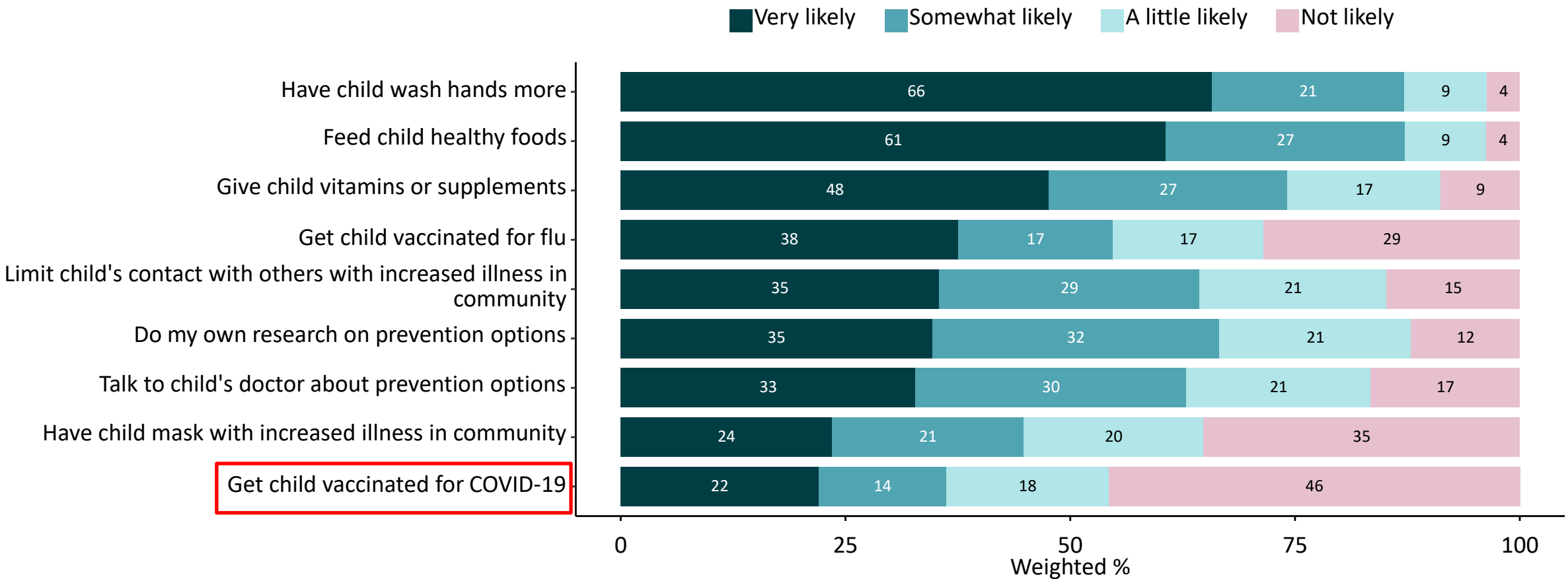


Current season week ending date refers to the 2024-2025 season only. For the 2023-2024 season, the corresponding week is represented

Data source: National immunization survey – Flu https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html

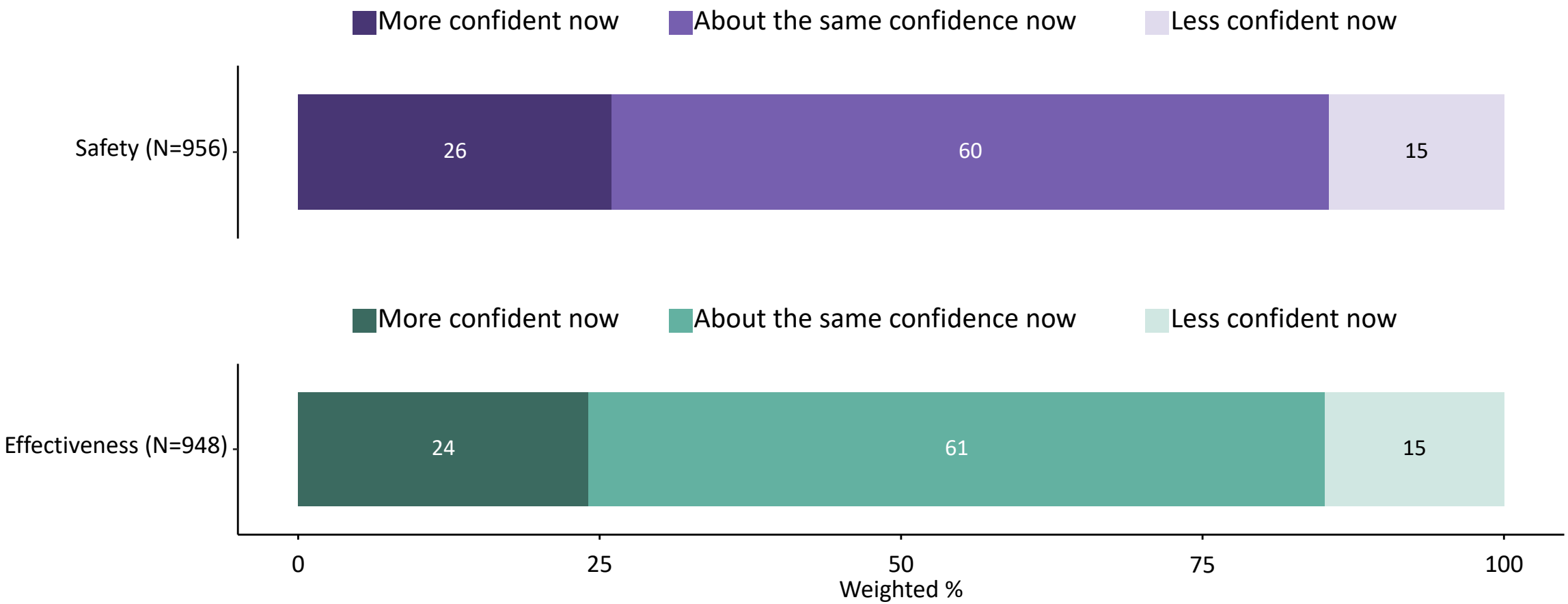
Accessed April 7, 2025

"How likely are you to take the following actions to help prevent your child from getting sick from a respiratory illness?" Results Among Parents of Child Ages 0–17 Years, Omnibus Surveys, November 7–29, 2024 (N=1,141)



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 ages 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 November (N=4,240). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

"Are you more or less confident in the safety/effectiveness of COVID-19 vaccines for children *now* compared to when they first came out?" Results Among Parents of Child Ages 0–17 Years Who Received at Least 1 Dose of a COVID-19 Vaccine, Omnibus Surveys, December 5, 2024–January 27, 2025



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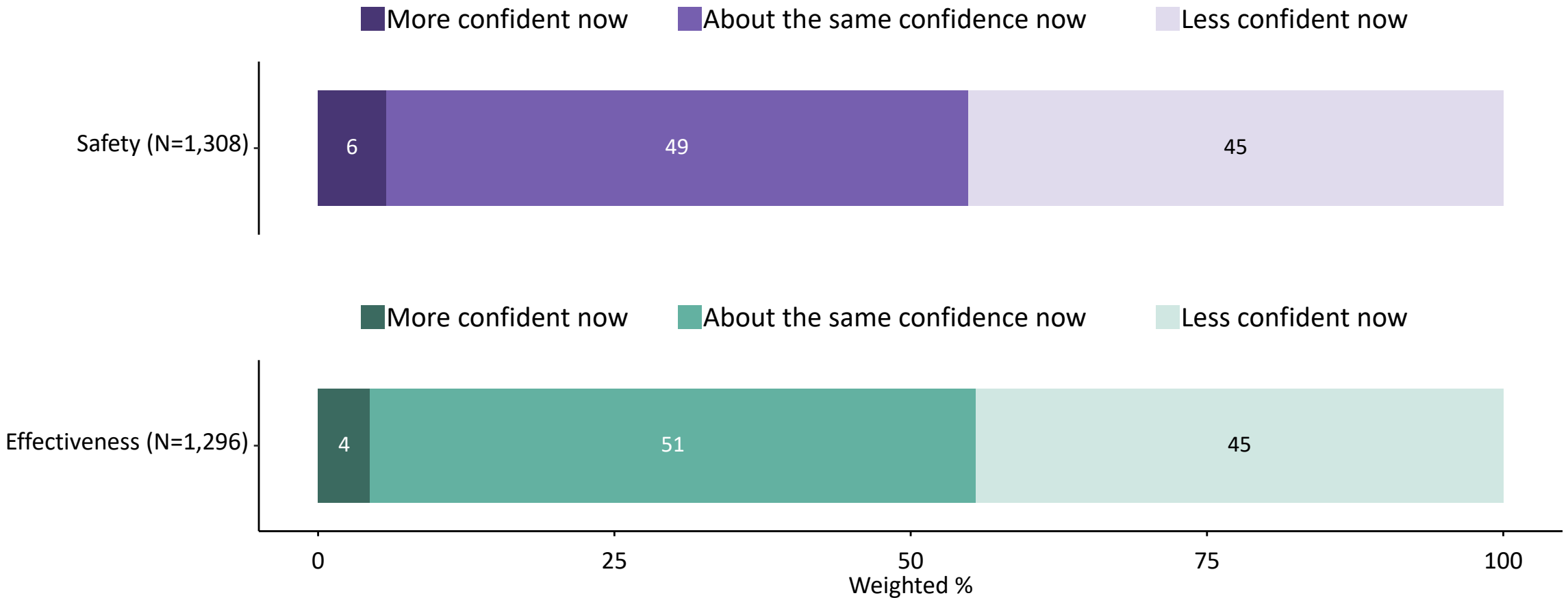
"Are you more or less confident in the safety/effectiveness of COVID-19 vaccines for children *now* compared to when they first came out?" Results Among Parents of Child Ages 0–17 Years Who Have Never Received a COVID-19 Vaccine, Omnibus Surveys, December 5, 2024—January 27, 2025



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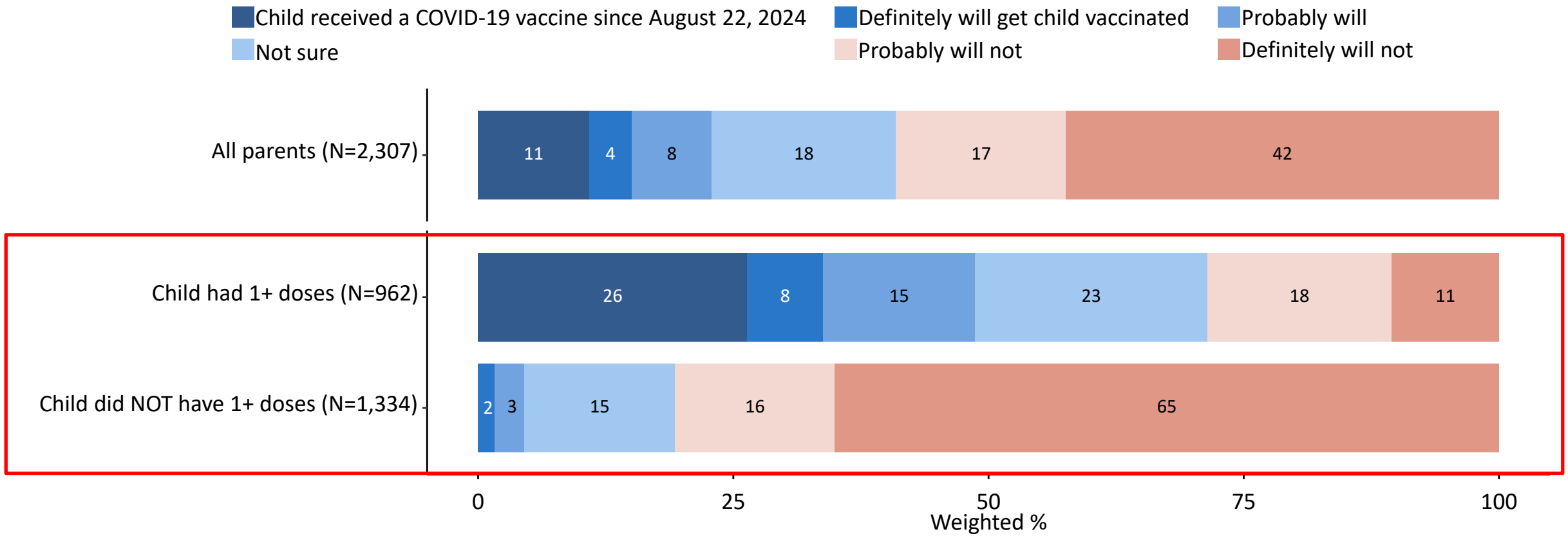
Child's 2024-2025 COVID-19 Vaccination Status And Parental Intent to Get Their Child Vaccinated, Results Among Parents of Children Ages 0–17 Years, by Receipt of Prior COVID-19 Vaccine(s), Omnibus Surveys, December 5, 2024–January 27, 2025 (N=2,312)



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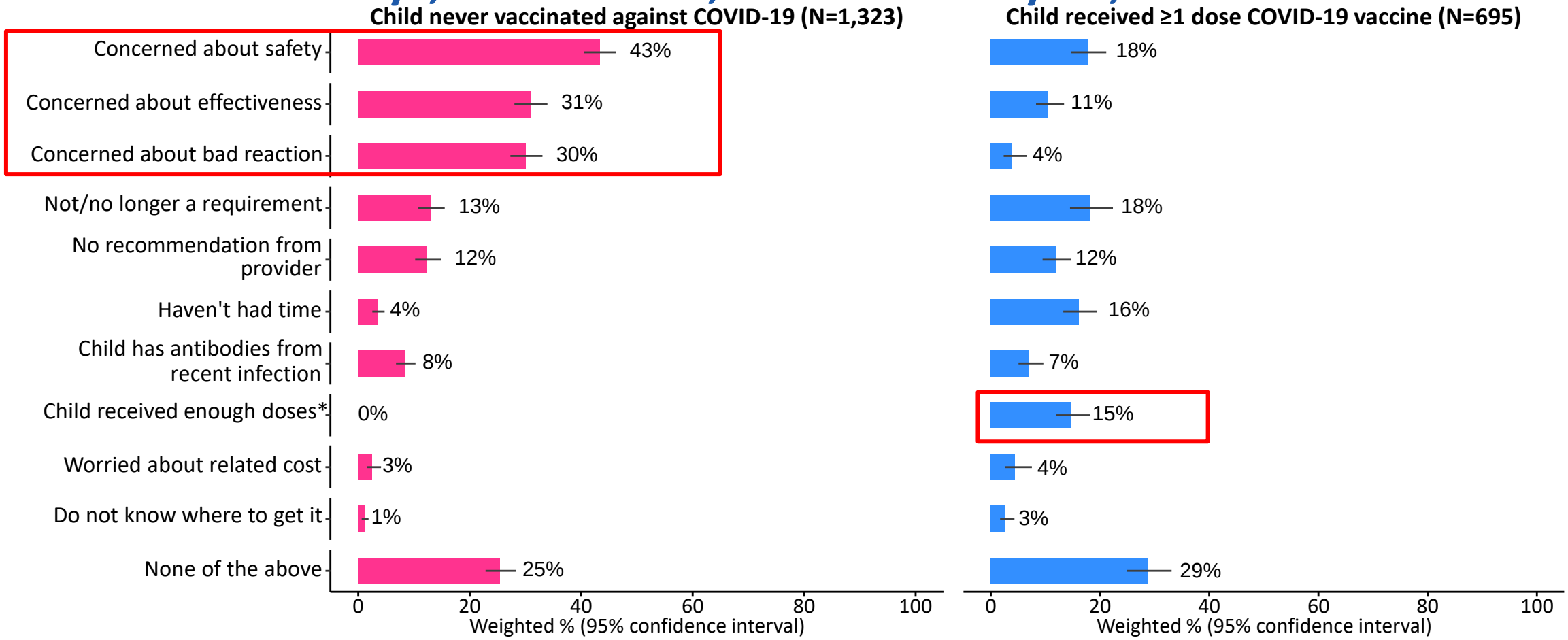
Reasons for Not Getting Child a 2024-2025 COVID-19 Vaccine, Among Parents of Child Ages 0–17, by Receipt of Prior COVID-19 Vaccine(s), Omnibus Surveys, December 5, 2024—January 27, 2025



*Option "Child received enough doses" only offered to parents of children who have received at least one dose of any COVID-19 vaccine.

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Recommendations in other countries

Summary of international COVID-19 booster* recommendations

	UK[1]	Canada[2]	Australia[3]	WHO	US
Older adults	**≥65 years:** 12 months **≥75 years and long-term care facility residents:** 6 months	**≥80 years and long-term care facility residents:** 6 months **65-79 years:** 12 months; *may receive every 6 months*	**≥75 years:** 6 months **≥65 years:** 12 months, *may receive every 6 months*	**Country dependent, often ≥75 or ≥80 years:** 6–12-month interval **Country dependent, often 50 or 60 years**: 12-month interval	**≥65 years:** 6 months
Adults (routine)	Not recommended	*May receive every 12 months*	*May receive every 12 months*	Not routinely recommended **Pregnant adults and adolescents:** dose in each pregnancy***	12 months
High-risk adults**	12 months	12 months	*May receive every 12 months*	12 months	12 months
Immunocompromised adults	6 months	6 months	12 months, *may receive every 6 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*
Children (routine)	Not recommended	*May receive every 12 months*	Not recommended	Not routinely recommended	12 months
High-risk children**	12 months	12 months	Not recommended	Not routinely recommended	12 months
Immunocompromised children	6 months	6 months	**Under 5 years:** not recommended ***5-17 years:*** *May receive every 12 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*

1 https://assets.publishing.service.gov.uk/media/66e7fbf624c4f1826d81bb32/Greenbook-chapter-14a-20240916.pdf 2 https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-guidance-covid-19-vaccines-2025-summer-2026.html 3 https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination/booster-doses

* Booster refers to people who have already completed an initial series. For people who are unvaccinated, more doses may be needed than are shown in this table

** Adults and children at increased risk of SARS-CoV-2 exposure **or** severe COVID-19 disease.

*** Ideally during in the second trimester or at any opportunity

Italics indicate discretionary/shared clinical decision-making recommendations

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Older adults	**≥65 years:** 12 months **≥75 years and long-term care facility residents:** 6 months	**≥80 years and long-term care facility residents:** 6 months **65-79 years:** 12 months; *may receive every 6 months*	**≥75 years:** 6 months **≥65 years:** 12 months, *may receive every 6 months*	**Country dependent, often ≥75 or ≥80 years:** 6–12-month interval **Country dependent, often 50 or 60 years**: 12-month interval	**≥65 years:** 6 months
Adults (routine)	Not recommended	*May receive every 12 months*	*May receive every 12 months*	Not routinely recommended **Pregnant adults and adolescents:** dose in each pregnancy***	12 months
High-risk adults**	12 months	12 months	*May receive every 12 months*	12 months	12 months
Immunocompromised adults	6 months	6 months	12 months, *may receive every 6 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*
Children (routine)	Not recommended	*May receive every 12 months*	Not recommended	Not routinely recommended	12 months
High-risk children**	12 months	12 months	Not recommended	Not routinely recommended	12 months
Immunocompromised children	6 months	6 months	**Under 5 years:** not recommended ***5-17 years:*** *May receive every 12 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*

1 https://assets.publishing.service.gov.uk/media/66e7fbf624c4f1826d81bb32/Greenbook-chapter-14a-20240916.pdf 2 https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-guidance-covid-19-vaccines-2025-summer-2026.html 3 https://www.health.gov.au/our-work/covid-19-vaccines/getting-your-vaccination/booster-doses

* Booster refers to people who have already completed an initial series. For people who are unvaccinated, more doses may be needed than are shown on this table

** Adults and children at increased risk of SARS-CoV-2 exposure **or** severe COVID-19 disease.

*** Ideally during in the second trimester or at any opportunity

Italics indicate discretionary/shared clinical decision-making recommendations

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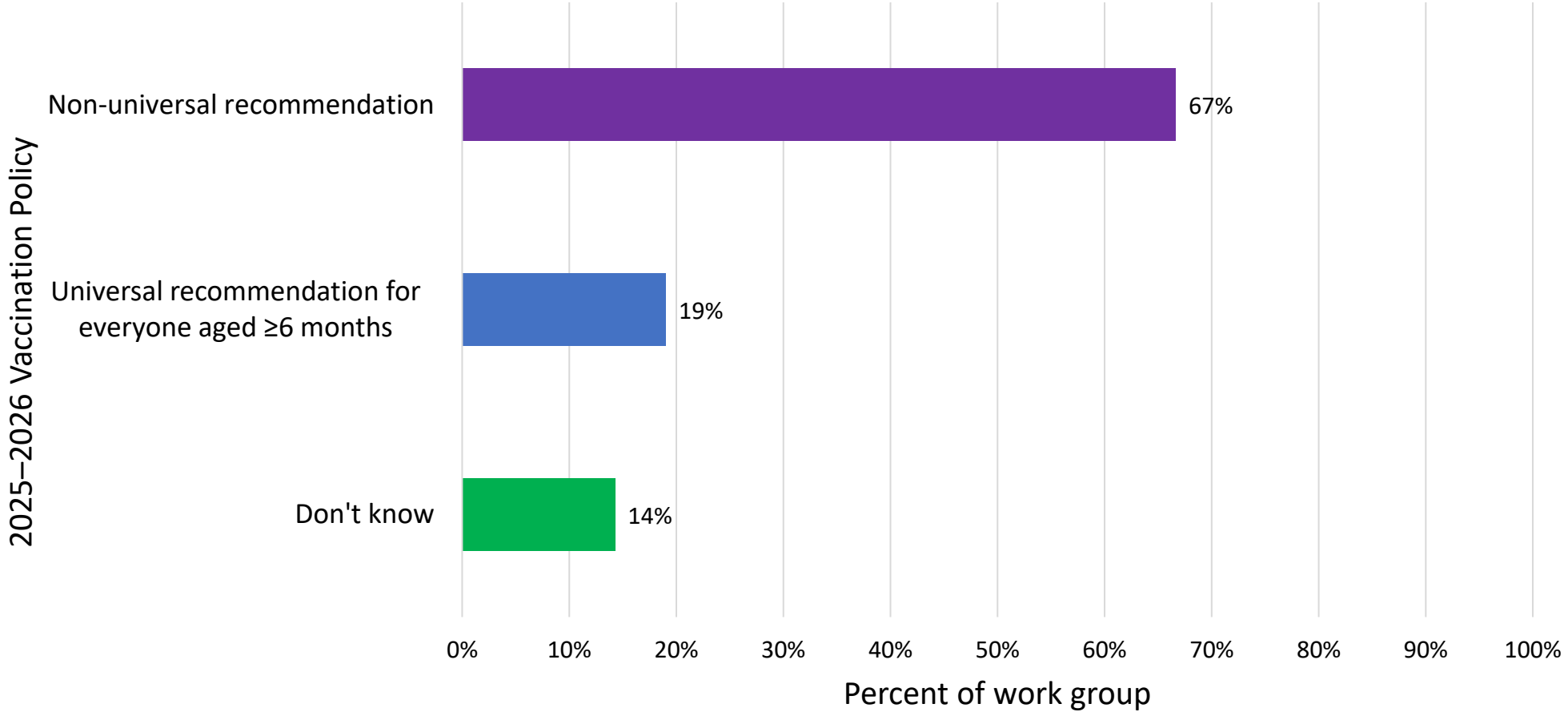
Work Group Interpretations

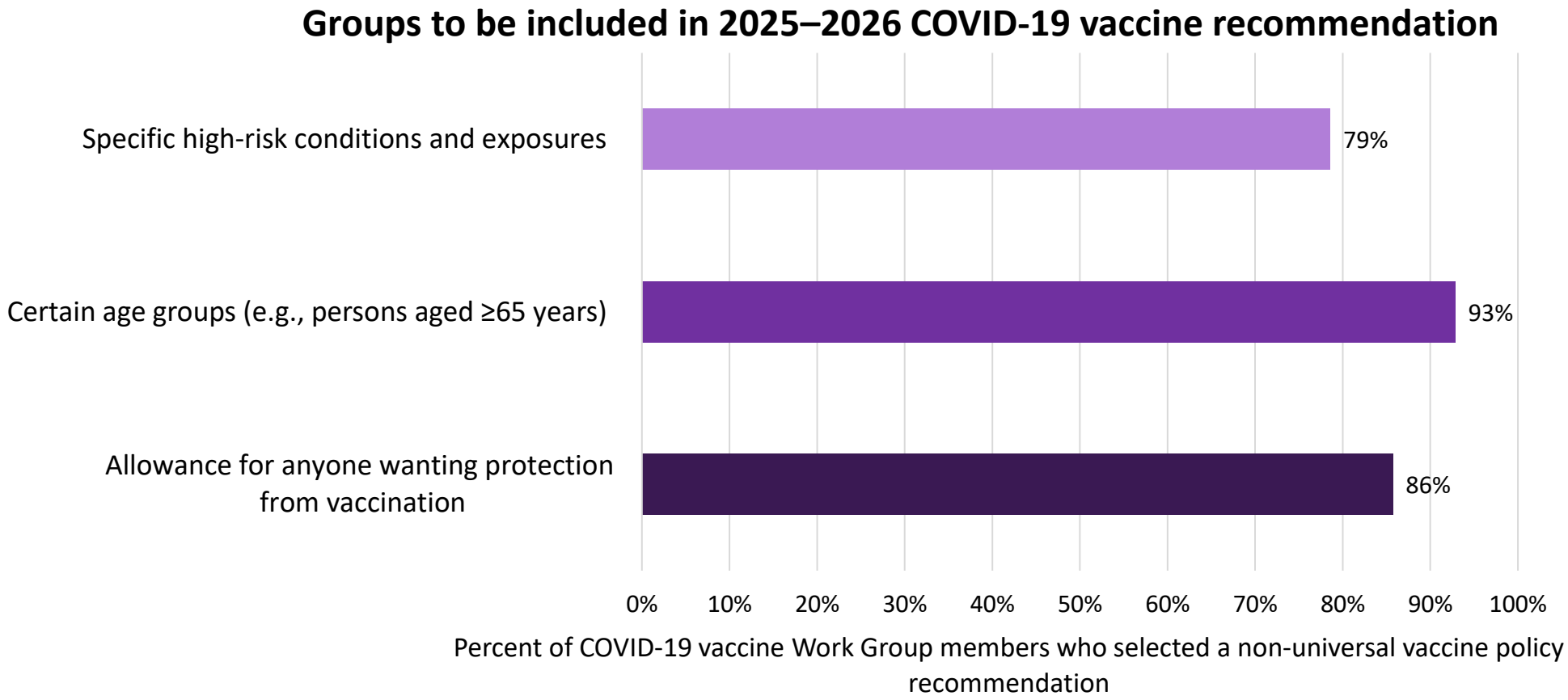
Initial Work Group interpretations

- When initially presented with 2025–2026 COVID-19 vaccine policy options in November 2024, the Work Group appreciated pros and cons of both risk-based and universal vaccine recommendations
- At that time, there was not yet a consensus on what the recommendation for the 2025–2026 COVID-19 vaccine should be
- The Work Group requested additional information to help inform the decision-making process on risk-factors for severe COVID-19, transmission and immunity, vaccine implementation and access, and cost-effectiveness

When polled on February 13, 2025, the majority of the work group supported a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



When polled on February 13, 2025, the Work Group supported all non-universal policy options*



* More than one response option could be selected.

Additional data presented to the Work Group (March – April 2025)

- Seroprevalence of SARS-CoV-2
- Long COVID
- COVID-19 vaccine coverage update
- Multisystem Inflammatory Syndrome in Children (MIS-C)

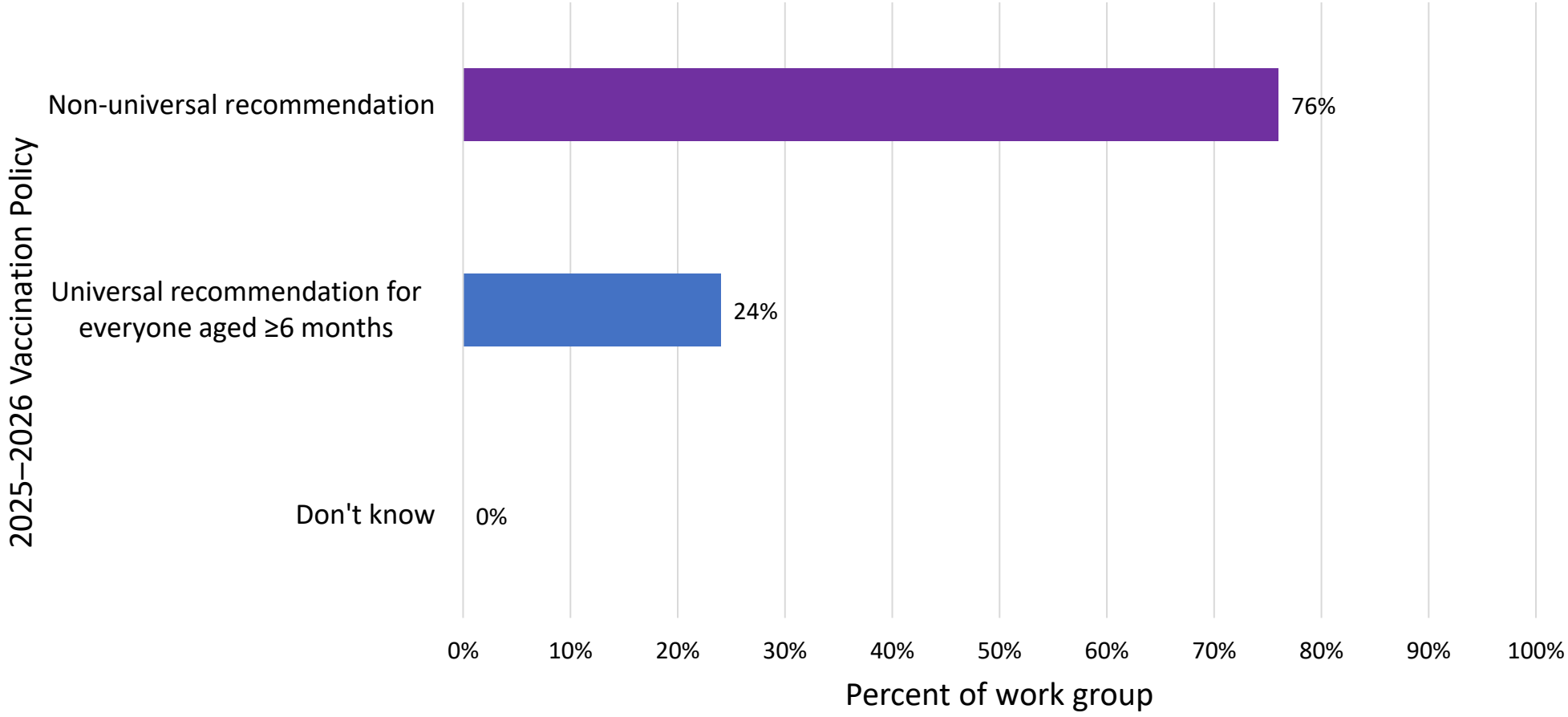
- Liaison feedback (see next slide)

Liaison feedback on a potential risk-based recommendation obtained from the following organizations (March – April 2025)

- American Academy of Family Physicians
- American Academy of Pediatrics
- Association of Immunization Managers
- American College of Physicians
- American Pharmacists Association
- American College of Obstetricians and Gynecologists

- Concerns were raised regarding implementation, communication, confidence in recommendations and equitable access to vaccination with a potential risk-based recommendation

When polled on April 3, 2025, the majority of the work group continued to support a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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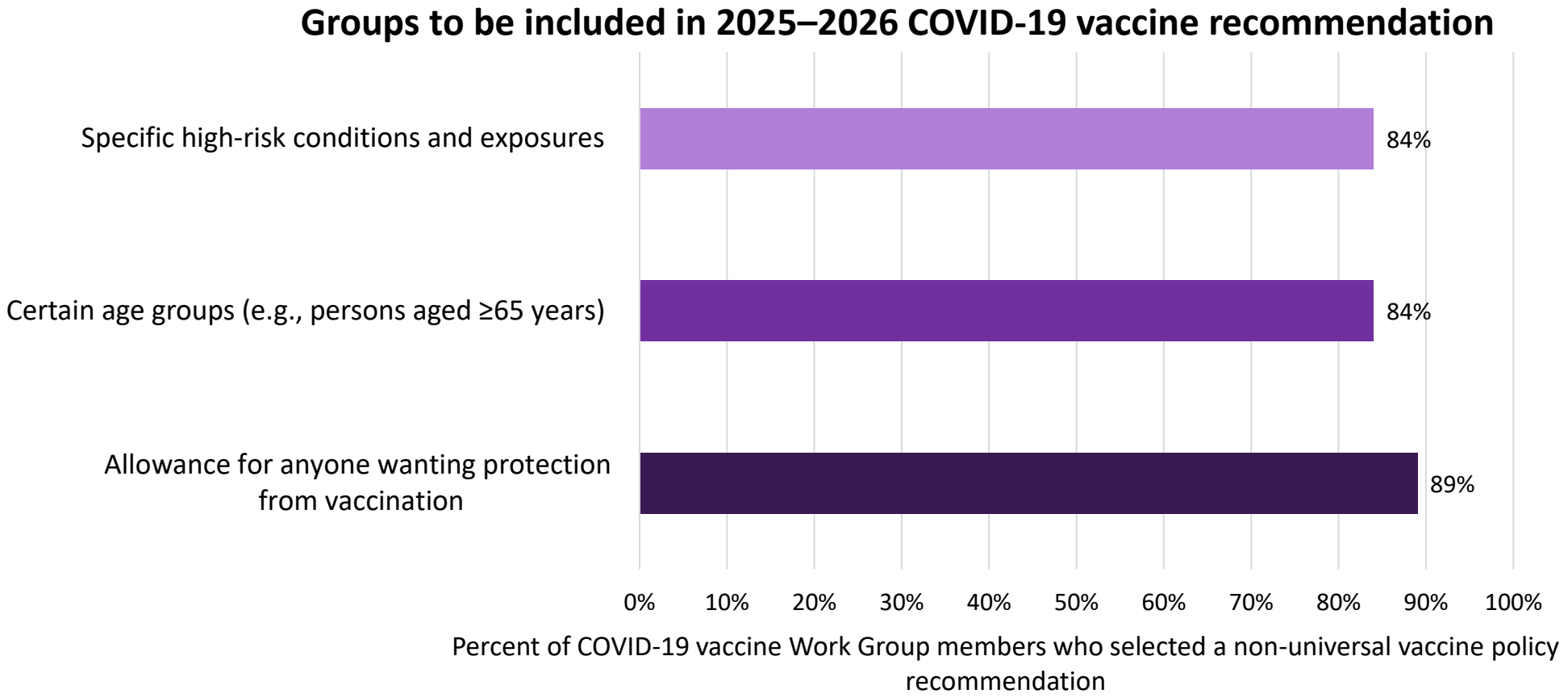
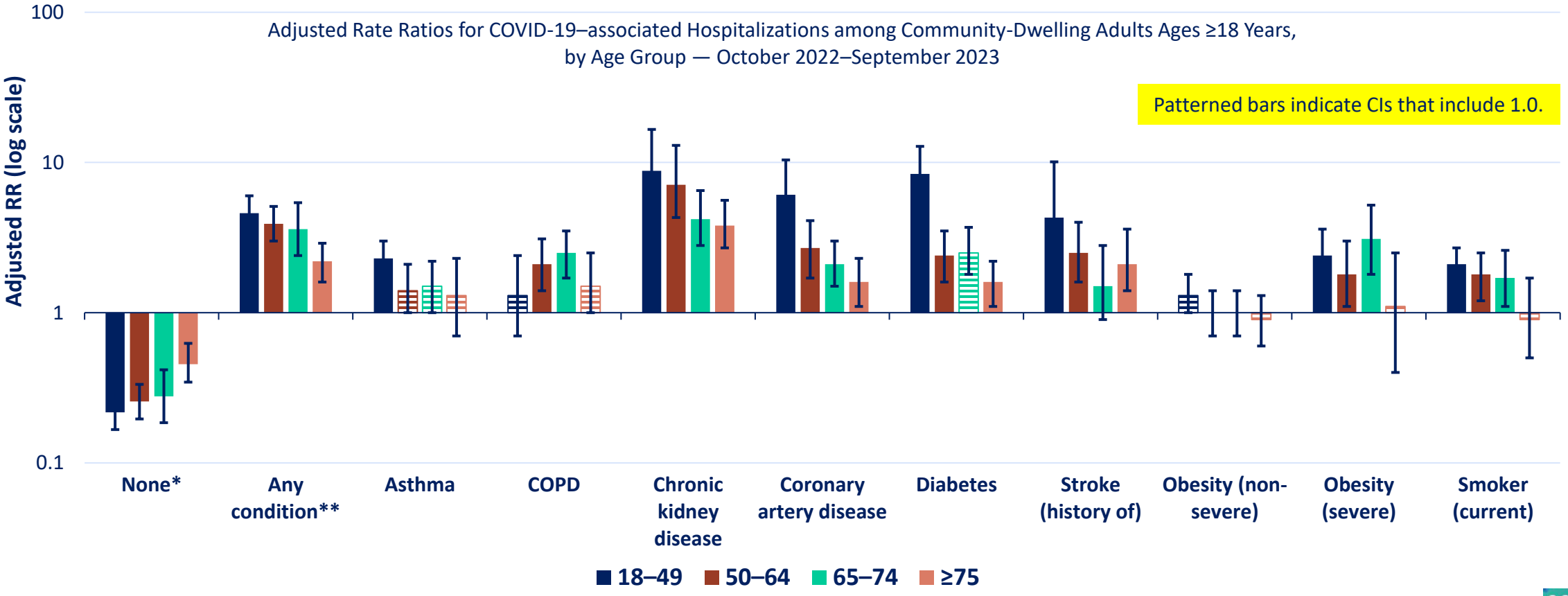


* More than one response option could be selected.

Risk for COVID-19–associated hospitalization is increased among community-dwelling adults ages ≥18 years with underlying medical conditions.



Abbreviations: RR, rate ratio; CI, confidence interval; COPD, chronic obstructive pulmonary disease.
* "None" refers to having none of the conditions examined in this analysis (asthma, COPD, diabetes, chronic kidney disease, coronary artery disease, stroke, severe obesity, and current smoking).
** "Any condition" refers to having at least 1 of these conditions. Notes: Non-severe obesity is defined as BMI 30–39kg/m². Severe obesity is defined as BMI ≥40kg/m². "Any condition" includes asthma, COPD, diabetes, chronic kidney disease, coronary artery disease, stroke, severe obesity, and current smoking. Rate ratios were estimated using multivariable Poisson models adjusted for sex, and race/ethnicity. "Smoker (current)" Includes people who quit smoking within the past 12 months. Data are limited to hospitalizations where COVID-19 is the likely reason for admission.

Discussion

- General thoughts on universal vs. risk-based recommendation for COVID-19 vaccination
  - Are there groups that clearly should **not** be recommended for vaccination with the 2025–2026 vaccine?
  - What data would be helpful in your decision making?
  - Is it still helpful to have a risk-based recommendation if most of the population (>74%) is considered “at risk”?
  - Should people at higher risk of infection and transmission (e.g., healthcare workers) be included in a risk-based recommendations?
- Will stable (i.e., universal) recommendations will increase uptake with time?
- Concerns about implementation challenges with risk-based recommendations?
- Any potential unintended implications or consequences of a recommendation change?
- Are there key decision points we have not captured here?

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- COVID-NET Team
- Immunization Safety Office
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases