Updates on Immunizations: ACIP meeting June 25-26th, 2025

Nava Yeganeh, MD, MPH
Vaccine Preventable Disease Control
Los Angeles County Department of Public Health

Disclaimer

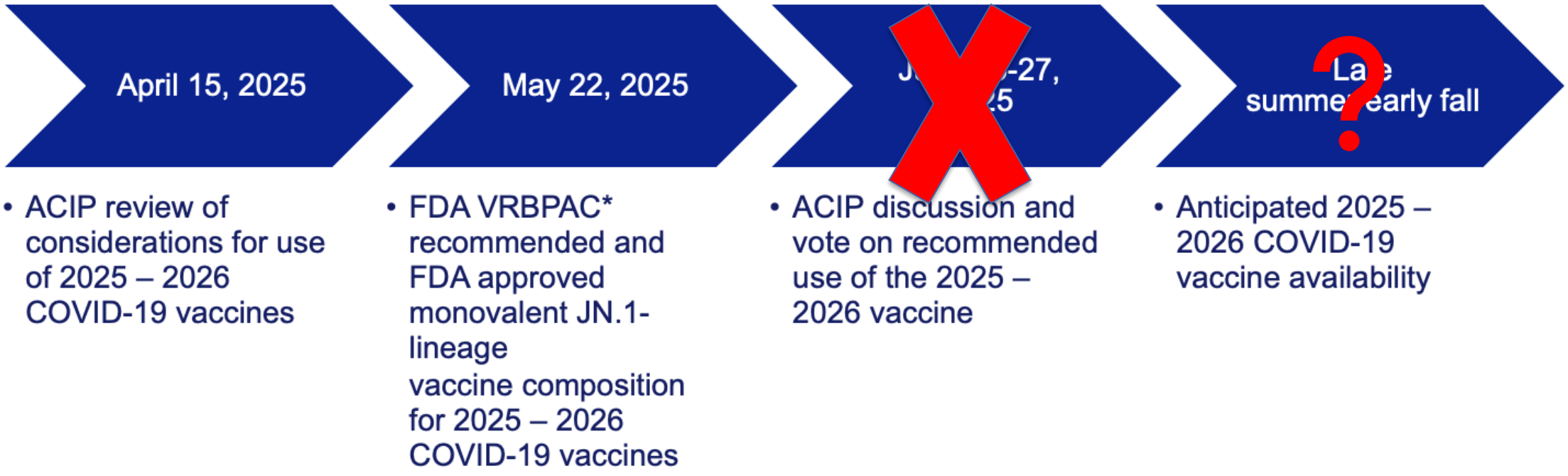
- Information about vaccines changes frequently.
- This presentation was current as of July 15, 2025
- More information and slides can be found on the ACIP website

Advisory Committee on Immunization Practices:

- The Advisory Committee on Immunization Practices (ACIP) is an apolitical advisory group established in March 1964 by the U.S. Surgeon General to provide expert advice on vaccine use to the Centers for Disease Control and Prevention (CDC) and the Secretary of Health and Human Services (HHS).
- This body determines which vaccines are recommended, for whom, if insurers cover them, and when they're available.

COVID-19 Vaccine recommendations

Normal COVID-19 vaccine approval process



New FDA leadership published new COVID framework in *New England Journal of Medicine:* Age 65+ years (all) Age 6 months-64 years with risk factors

FDA advisory group meets

RFK Jr posts on social media

CDC immunization schedules revised

RFK Jr (HHS sec) terminates all 17 ACIP members

RFK Jr (HHS sec) hires 8 new ACIP members. In general, less experienced.

ACIP meets—no vote on COVID-19 vaccines

May 20 | May 22 | May 27 | May 30 | June 9 | June 11 | June 25

Pregnancy and recent pregnancy are listed as risk factors.

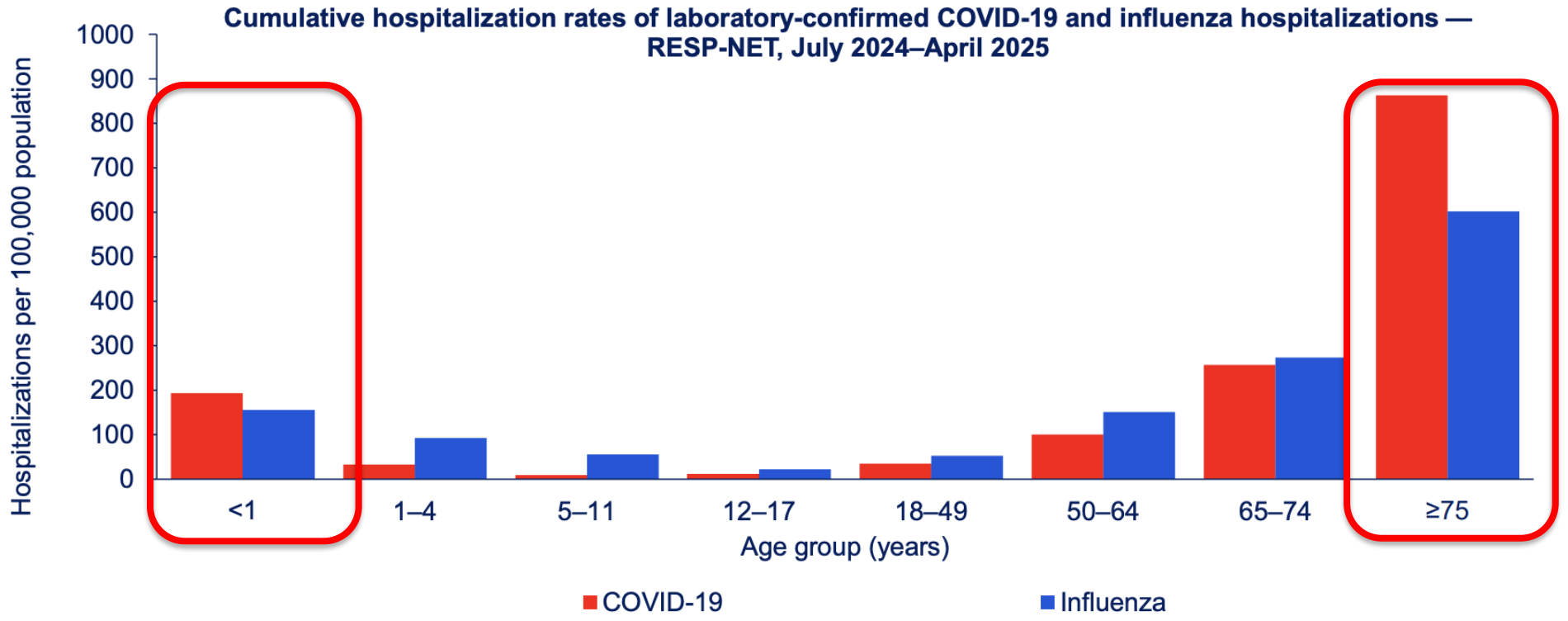
Chose JN.1. (LP.8.1)
No discussion of framework

Exclude healthy children and healthy pregnant women

Children: shared clinical decision-making.
Pregnancy: recommendation removed.

? ?

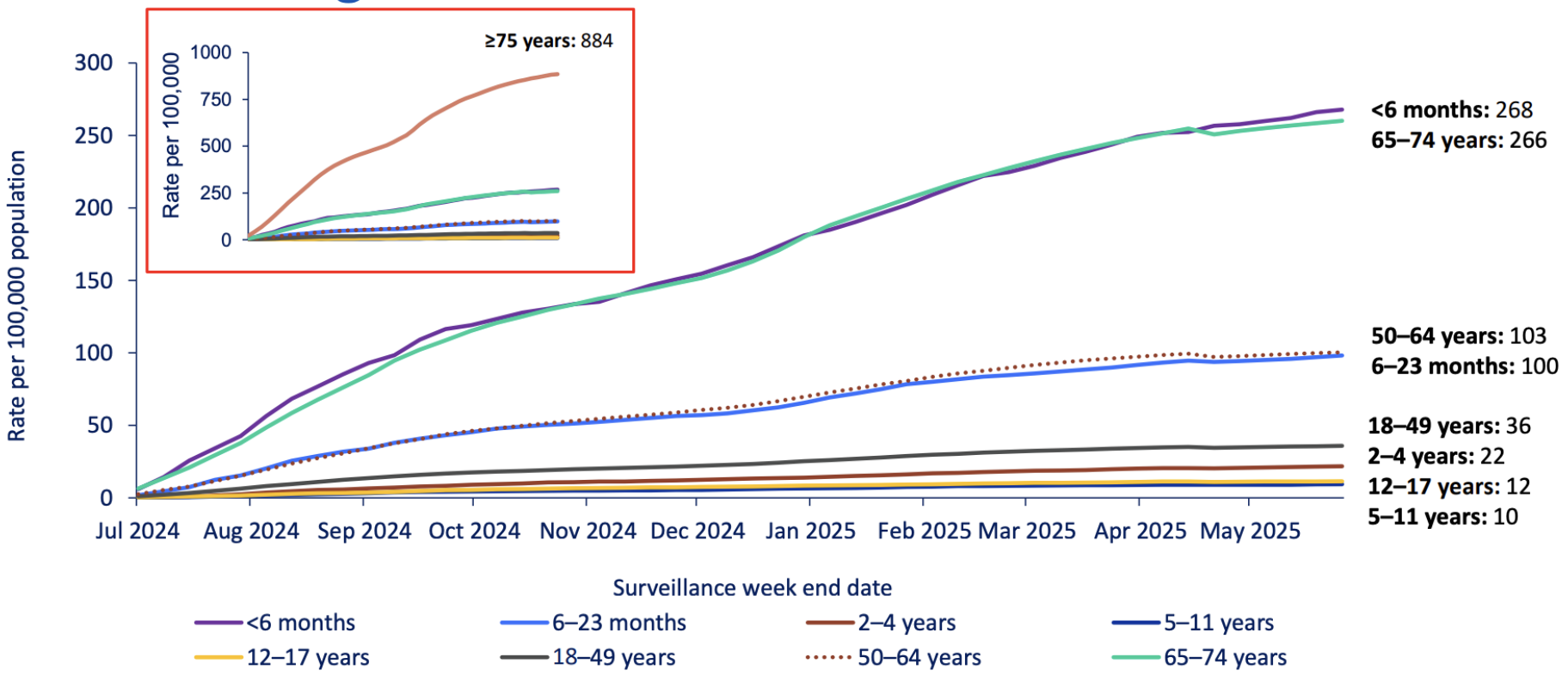
From July 2024 – April 2025, a period that included a high severity influenza season[1], more infants <1 and adults ≥75 had hospitalizations associated with COVID-19 than influenza.



Cumulative hospitalization rates with laboratory-confirmed SARS-CoV-2 and influenza hospitalizations — RESP-NET, July 2024–April 2025. Note that influenza surveillance is conducted from October–April annually. Data source: https://www.cdc.gov/resp-net/dashboard/. Note that rates are not adjusted for testing nor limited to admissions where the respiratory infection is the likely primary reason for admission. [1]https://www.cdc.gov/flu/php/surveillance/in-season-severity.html

Slides from ACIP meeting June 25, 2025

Cumulative COVID-19-associated hospitalization rates are highest among adults aged ≥75 years, followed by adults aged 65–74 years and infants aged <6 months.

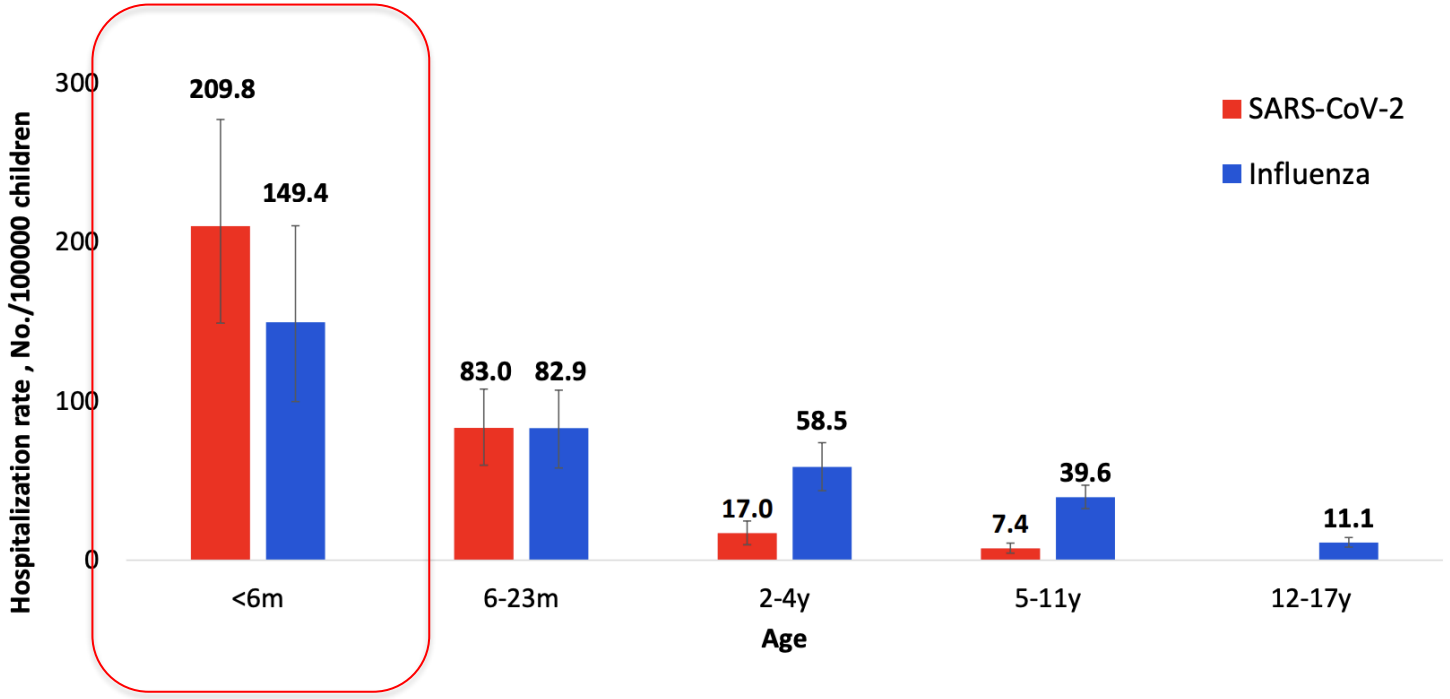


Weekly rates of COVID-19–associated hospitalizations per 100,000 population by age group—COVID-NET, July 2024–May 2025

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

Slides from ACIP meeting June 25, 2025

The highest rates for COVID-19 in the New Vaccine Surveillance Network were observed in infants <6 months of age.



Pediatric COVID-19 and influenza hospitalization rates among children <18 years, New Vaccine Surveillance Network (NVSN), July 2024- March 2025. Rate estimates with standard error >30 due to few detections are not presented. Annual rates presented July – June of each season, with exception of 2024-2025, which represents July 2024 – March 2025.
NVSN, unpublished data

- No COVID-19 vaccine products are approved for infants ages <6 months
  - Dependent on maternal vaccinations
- 22% admitted in the ICU
- 71% of those <6 months hospitalized did not have an underlying conditions

Slides from ACIP meeting June 25, 2025

Summary of 2024-2025 COVID-19 season

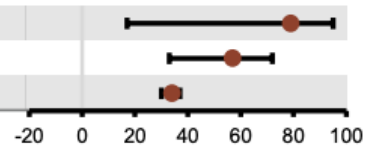
- More infants under 1 year and adults over 75 years were hospitalized for COVID than for for flu.
- Hospitalizations for infants under 6 months are nearly identical to those aged 65-74 years.
- 1 in 4 children hospitalized for COVID required ICU admission (April 2024-March 2025).
  - 89% of hospitalized children had no record of receiving the most recently recommended COVID vaccine.
- Adults 65+ comprise two-thirds of all hospitalizations, with most having at least one underlying medical condition.
  - 65% of hospitalized adults had no recent COVID vaccine.

COVID-19 Vaccine Effectiveness

VE of 2024-2025 COVID-19 vaccine doses against *emergency department/urgent care encounters* — VISION

September 2024 – May 2025

Age group | COVID-19 vaccination status	Total encounters	SARS-CoV-2-test-positive, N (%)	Median interval since last dose among those vaccinated, days (IQR)	Adjusted vaccine effectiveness % (95% CI)
No updated 2024-2025 COVID-19 vaccine dose*				
9 months-4 years	31,060	809 (3)	392 (282-662)	**Ref**
5-17 years	38,870	926 (2)	972 (710-1,116)	**Ref**
≥18 years	200,933	12,927 (6)	1,068 (742-1,224)	**Ref**
2024-2025 COVID-19 dose received 7-179 days earlier				
9 months-4 years	393	2 (1)	64 (30-98)	**79 (17 to 95)**
5-17 years	2,208	22 (1)	81 (44-122)	**57 (33 to 72)**
≥18 years	40,043	1,694 (4)	89 (50-129)	**34 (30 to 37)**



CDC, unpublished data

* Includes all individuals who did not receive a 2024-2025 COVID-19 vaccine. For those aged ≥5 years, this includes unvaccinated persons and persons who were vaccinated with ≥1 original monovalent or bivalent COVID-19 doses. For those aged <5 years, both those in the referent group and those in the vaccinated group were required to have completed an initial series. The 2024-2025 dose could have been part of the initial series or in addition to the initial series.

Vaccine effectiveness was calculated by comparing the odds of COVID-19 vaccination in case-patients and control-patients using the equation: (1 − adjusted odds ratio) x 100%. Odds ratios were estimated by multivariable logistic regression. The odds ratio was adjusted for age, sex, race and ethnicity, calendar day, and geographic region.

- Overall vaccine effectiveness (VE) against ER/urgent care encounters for the 2023-2024 season was:
  - 79% for 9 months-4 years
  - 57% for 5-17 years
  - 34% for 18+ years.

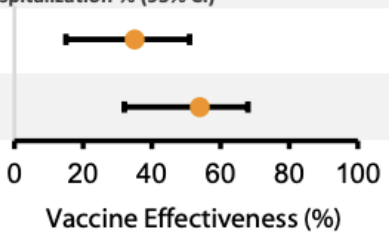
Slides from ACIP meeting June 25, 2025

Maternal COVID-19 vaccination:

Overcoming COVID-19: Effectiveness* of maternal vaccination† in prevention of COVID-19–associated *hospitalization* among infants§

March 9, 2022 – May 31, 2023

Age group of infant	No. vaccinated/Total no. (%) Case-patients	Control patients	Interval between last vaccine dose and infant hospitalization, days (IQR)	Effectiveness of Maternal Vaccination against Infant Covid-19 Hospitalization % (95% CI)
0-5 months	82/377 (22)	94/339 (28)	236 (185–300)	**35 (15–51)**
0-2 months	43/227 (19)	63/214 (29)	219 (152–264)	**54 (32–68)**



Simeone & Zambrano et al., MMWR, 2023: https://www.cdc.gov/mmwr/volumes/72/wr/mm7239a3.htm.

* VE estimates were based on odds of maternal vaccination during pregnancy in case-patients versus control patients, adjusted for U.S. Census Bureau region, admission date (monthly), age (in months), sex, and race and ethnicity (non-Hispanic Black or African American, non-Hispanic White, non-Hispanic other, Hispanic or Latino of any race, or unknown). Study site was included as a repeated effect. VE was calculated as (1 − adjusted odds ratio) x 100%.

† Maternal vaccination status was based on the last date of a COVID-19 mRNA vaccine dose: unvaccinated was defined as mothers who had not received any vaccine dose before or during pregnancy, and vaccinated was defined as mothers who received their last dose of a COVID-19 mRNA vaccine between the first day of pregnancy and 14 days before delivery. Among those vaccinated during pregnancy, mothers could have received ≥1 dose during pregnancy. Mothers could receive 1 dose of Ad.26.CoV2.S (Janssen [Johnson & Johnson]) vaccine before or during pregnancy and 1 dose of an mRNA vaccine during pregnancy. Mothers who received only 1 dose of an mRNA vaccine were considered partially vaccinated and were excluded from the analysis. Mothers whose last vaccine dose occurred before pregnancy were excluded from the analysis.

§ Infants were excluded from analysis if they were born to mothers who had received their most recent dose before pregnancy, received only 1 dose of an mRNA vaccine, received their most recent vaccine dose within 14 days of delivery, received only 1 dose of a viral vector vaccine, or whose vaccination status could not be verified or whose timing of vaccination was unknown.

16

- Maternal vaccination showed protection against hospitalization:
  - 35% protection for infants 0-5 months
  - 54% for infants 0-2 months.

Slides from ACIP meeting June 25, 2025

ACOG Asserts that Data Presented at ACIP Support Maternal Immunization

News Releases | Jun 27, 2025

Share | Print

ACOG Asserts that Data Presented at ACIP Support Maternal Immunization

ellowship

The following is a statement from Steven J. Fleischman, MD, MBA, FACOG, president of the American College of Obstetricians and Gynecologists (ACOG):

ADVERTISEMENT

Special project

Vaccine Integrity Project

HOME | **REPORTS** | **VIEWPOINTS** | **UPDATES**

CIDRAP's Vaccine Integrity Project is an initiative dedicated to safeguarding vaccine use in the U.S. so that it remains grounded in the best available science, free from external influence, and focused on optimizing protection of individuals, families, and communities against vaccine-preventable diseases. Over the coming months, facilitated sessions will be held to gather critical feedback to understand what may be needed to ensure the integrity of the U.S. vaccine system, including vaccine evaluations and clinical guidelines based on rigorous and timely reviews. The Vaccine Integrity Project is supported by an unrestricted gift from Alumbra, a foundation established by philanthropist Christy Walton.

CIDRAP will provide continual updates on the initiative's progress.

AAP will continue to publish its own vaccine recommendations after CDC advisers sow distrust

Case 1:25-cv-11916 Document 1 Filed 07/07/25 Page 1 of 42

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, and JANE DOE,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MARTY MAKARY, in his official capacity as Commissioner of the Food and Drug Administration; FOOD AND DRUG ADMINISTRATION; JAY BHATTACHARYA, in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; MATTHEW BUZZELLI, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive,

Case No. 1:25-cv-11916

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

LAC Guidance for providers regarding COVID-19 vaccines

- Based on the information presented, LAC DPH continues to recommends that all individuals age 6 months and older should have access and the choice to receive currently authorized COVID-19 vaccines, with an emphasis on protecting higher risk individuals, such as infants, older adults, pregnant individuals, and others with underlying conditions putting them at increased risk of serious disease.

RSV Immunizations

Summary of recommendations

In 2023 two products were approved by FDA and subsequently recommended by CDC and ACIP

Maternal RSV vaccine
Abrysvo, Pfizer

Pregnant women 32 through 36 weeks' gestation

Administer September through January in most of the continental United States†

Nirsevimab
Beyfortus, Sanofi & AstraZeneca

All infants ages <8 months*

Second season dose for children ages 8–19 months at increased risk of severe RSV disease

Administer October through March in most of the continental United States† (as early as possible¥)

New

Clesrovimab
Enflonasia, Merck
Approved by FDA on 6/9/2025

All infants ages <8 months*

Administer October through March in most of the continental United States† (as early as possible¥)

*_**Either**_ maternal RSV vaccine or nirsevimab is given to protect infants against severe RSV disease – only one is needed in most instances

Immunizations to prevent RSV disease in infants

Nirsevimab effectiveness:

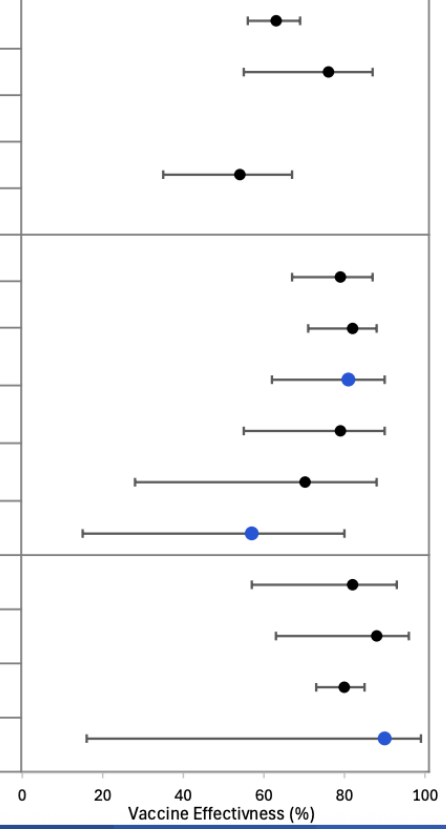
- 63-75% ED visits
- 79-82% hospitalization
- 80-82% critical illness requiring ICU admission

Maternal vaccination:

- 54% ED encounters
- 70-79% hospitalizations

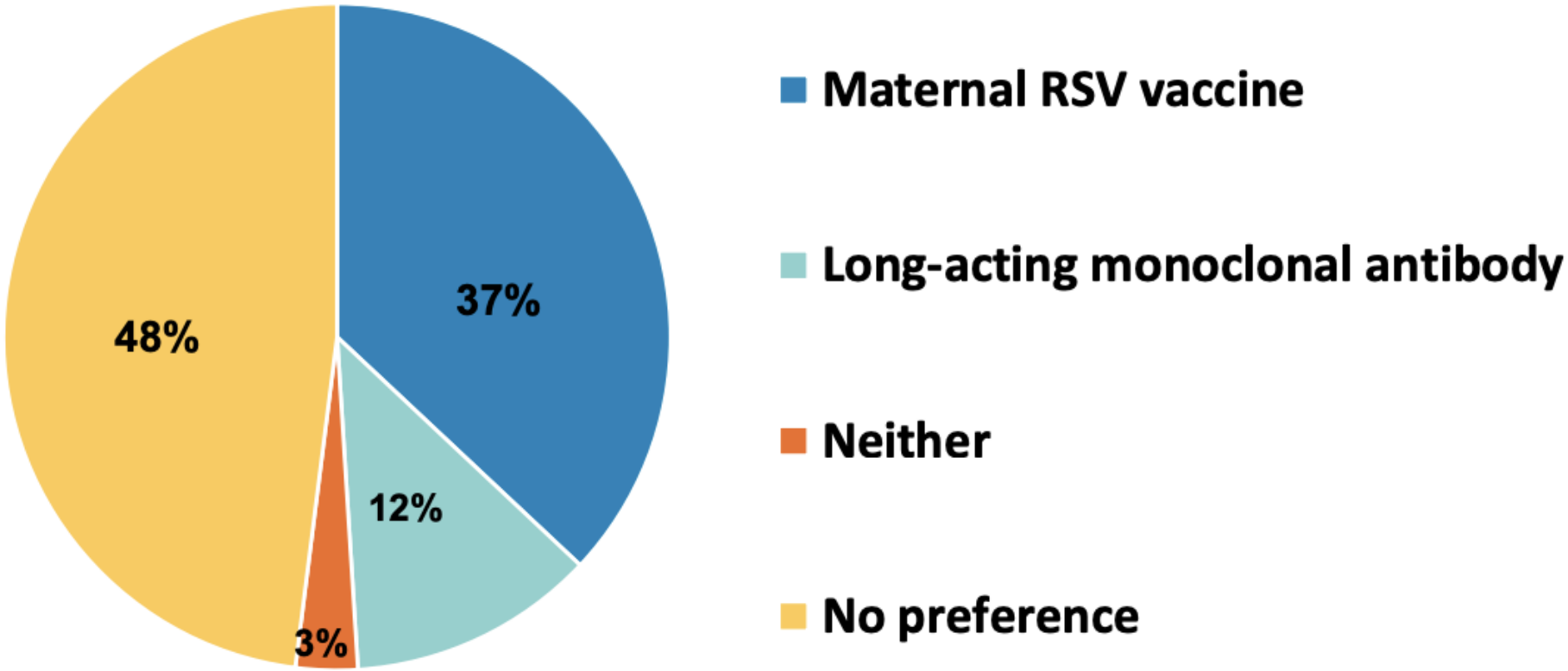
Summary of RSV prevention product effectiveness (PE) among infants in their first RSV season, 2024–2025

Outcome	Product	CDC Network	Product Efficacy*/Effectiveness (95% CI)
RSV-associated ED visit	Nirsevimab	VISION	63 (56-69)
		NVSN	76 (55-87)
		Clinical Trial	Not Applicable
	Maternal Vaccine	VISION	54 (35-67)
		Clinical Trial	Not Applicable
RSV-associated hospitalization	Nirsevimab*	VISION	79 (67-87)
		NVSN	82 (71-88)
		Clinical Trial	81 (62-90)
	Maternal Vaccine†	VISION	79 (55-90)
		NVSN	70 (28-88)
		Clinical Trial	57 (15-80)
RSV-associated Intensive Care Unit (ICU) admission	Nirsevimab*	VISION	82 (57-93)
		NVSN	88 (63-96)
		Overcoming	80 (73-85)
		Clinical Trial	90 (16-99)



*Jones et al. *MMWR* 2023. Available: https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm
†Kampmann et al. *NEJM* 2023. Available: https://www.nejm.org/doi/full/10.1056/NEJMoa2216480

Parental preference for RSV immunization products if both were available, safe and effective among adults aged 18-49 years with children, CASCADIA Study, Oregon and Washington, U.S., April-May 2023 (n=1082)



Kuntz et al. Attitudes about Respiratory Syncytial Virus (RSV) Vaccination during Pregnancy, and Infant Monoclonal Antibodies for RSV, 2024

Clesrovimab

Outcome	Efficacy estimate[1] % (95% CI)	Concerns in certainty assessment
Benefits, through 150 days of follow-up		
1. RSV-associated medically attended LRTI	60.4 (44.1, 71.9)	Not serious (indirectness)[2]
2. RSV-associated LRTI with hospitalization	90.9 (76.2, 96.5)	Not serious (indirectness)[2]
3. RSV LRTI with ICU admission[3]	100.0 (24.0, 100.0)	Serious (imprecision)[4] Not serious (indirectness)[2]
4. All-cause medically attended LRTI	13.1 (-0.6, 24.8)	Serious (imprecision)[5] Not serious (indirectness)[2]
5. All-cause LRTI with hospitalization	49.0 (26.7, 64.5)	Not serious (indirectness)[2]

1. Estimates and 95% CI were estimated from the modified Poisson regression with robust variance method.
2. Concern for indirectness: the trial excluded infants who were palivizumab-eligible and took place during a season with disrupted seasonality due to COVID-19. This was deemed not serious.
3. Outcome was not a trial endpoint and was assessed post-hoc.
4. Serious concern for imprecision: the number of study participants did not meet optimal information size.
5. Serious concern for imprecision: the confidence interval containing estimates for which different policy decisions might be considered.

Additional notes

- Clesrovimab has a shorter half-life than nirsevimab (44 days vs 71 days)
  - efficacy against severe RSV lasts 150 days
- Same dose given no matter weight/age of baby
- Clesrovimab and nirsevimab trial outcomes had different definitions, making direct comparisons in efficacy challenging
- Multiple manufacturers in the same market allow for:
  - Multiple products with different binding sites are beneficial if resistance mutations develop to either product
  - If one product has insufficient supply in the United States, the other product reduces the risk of a shortage.
  - Competitive pricing of products may be created by market competition

Expected Clesrovimab Storage and Handling*

Store refrigerated between 2°C and 8°C (36°F and 46°F).

Use within 48 hours of removing from refrigerator.

- May be kept at room temperature, between 20°C and 25°C (68°F and 77°F), for a maximum of 48 hours

Do *not* freeze.

Do *not* shake.

Protect from light.

Choose One Product to Prevent Severe RSV Disease in Infants

Maternal RSV vaccination
- Pfizer Abrysvo

- or -

Infant RSV antibody
- Nirsevimab
- Clesrovimab*

Most infants will *not* need both maternal vaccination and an RSV antibody.

Considerations for Counseling Patients Regarding Maternal RSV Vaccine and Infant RSV Antibodies

Maternal RSV vaccine 	Immediate protection for baby after birth No injection for the infant Potentially reduced protection in some situations (e.g., mother is immunocompromised or infant born soon after vaccination) Potential risk for hypertensive disorders of pregnancy
Infant RSV antibody 	Direct receipt of antibodies rather than relying on transplacental transfer Protection may wane more slowly than maternal RSV vaccine Side effects are usually mild and resolve quickly; hypersensitivity reactions are uncommon but have been reported Delayed administration could leave the infant unprotected[1]

RSV recommendations

- Along with ACIP, LAC DPH recommends that providers administer RSV monoclonal antibody (nirsevimab or clesrovimab) to all infants younger than 8 months entering their first RSV season (October–March) whose birth parent did not receive an RSV vaccine during pregnancy.
- For children aged 8–19 months at increased risk of severe RSV, **only nirsevimab** is recommended.

Influenza vaccine and thimerosal

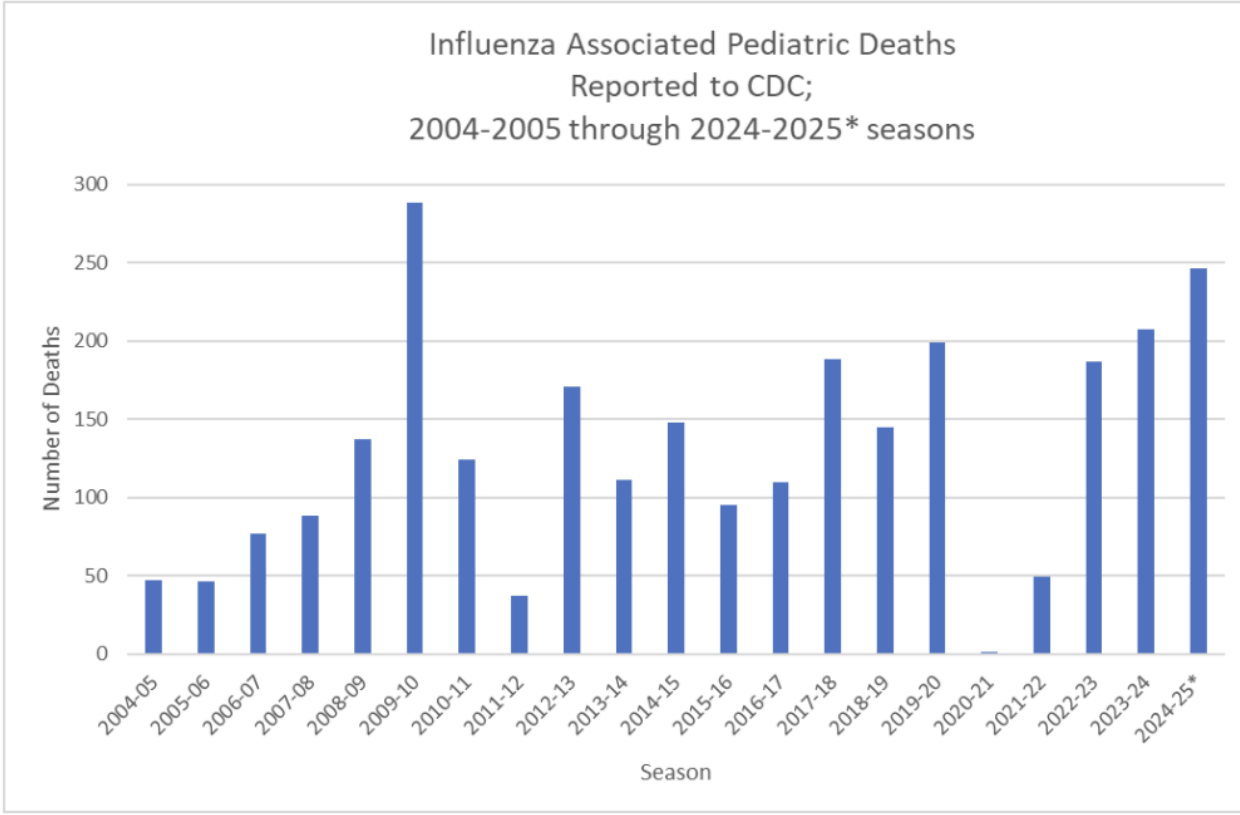
Influenza Severity Assessment by Season and by Age Group

	Severity Classification by Age Group			
Influenza Season*	**0-17 years**	**18-64 years**	**≥65 years**	**All Ages**
2009-2010	Very High	Moderate	Low	Moderate
2010-2011	Moderate	Moderate	Moderate	Moderate
2011-2012	Low	Low	Low	Low
2012-2013	Moderate	Moderate	High	Moderate
2013-2014	Moderate	Moderate	Moderate	Moderate
2014-2015	Moderate	Moderate	High	High
2015-2016	Low	Moderate	Low	Moderate
2016-2017	Moderate	Moderate	Moderate	Moderate
2017-2018	High	High	High	High
2018-2019	Moderate	Moderate	Moderate	Moderate
2019-2020	High	High	Moderate	Moderate
2021-2022	Low	Low	Low	Low
2022-2023	High	Moderate	Moderate	Moderate
2023-2024	Moderate	Moderate	Moderate	Moderate
2024-2025	High	High	High	High

*Severity assessment was not completed for 2020-2021 season because of minimal influenza activity

Pediatric Death

- 246 deaths
- All age groups affected
  - 0-5 months: 7%
  - 6-23 months: 13%
  - 2-4 years: 18%
  - 5-11 years: 37%
  - 12-17 years: 26%
- 42% had no known high risk underlying medical condition
- 40% had a bacterial co-infection of a sterile site
- 89% of those eligible for influenza vaccination were not fully vaccinated



Through June 7, 2025 https://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html 6

Thimerosal background

- Thimerosal is a mercury-containing organic compound (50% mercury)
  - Degraded to ethylmercury (vs methylmercury, found in fish)
  - Since the 1930s, it has been widely used as a preservative in many biological and drug products, including vaccines as preservative
  - Amount in childhood immunizations similar to eating 3 oz of can fish
  - In 1999, the Public Health Service (including the FDA, National Institutes of Health, CDC, and Health Resources and Services Administration), along with the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) concluded that because of scientific uncertainty at the time, it was prudent to reduce childhood exposure to mercury from all sources, including vaccines, to the extent feasible.

Thimerosal at ACIP

- Lyn Redwood RN, private citizen and former president of the Children's Defense Fund, gave a presentation of thimerosal safety
  - In previous interviews, Ms. Redwood has attributed her son's autism to thimerosal
  - Previously, only CDC and scientists that have been vetted by the CDC present at ACIP
  - Presentation was not reviewed by CDC
  - CDC posted a PDF document listing 17 pages of studies demonstrating safety of thimerosal. This document was removed by HHS secretary
- ACIP voted to recommend all adults, children and pregnant persons receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

"To the best of my knowledge, the study in rats referred to in the planned CDC presentation by Lyn Redwood listing Berman RF as first author does not exist," Robert F Berman, Ph.D., professor emeritus at the University of California Davis, said.

"I have not published a paper with that title or with that set of co-authors in the journal Neurotoxicology in 2008. Also, none of my research has made any statements about possible thimerosal effects on microglia in the brain or resulting in neuroimmune effects," Berman said.

Thimerosal-containing vaccines and neurodevelopmental outcomes
Review of the evidence

Thimerosal is an ethylmercury-containing compound that was used for decades in the United States as a preservative in multi-dose vials of vaccines and other products to prevent growth of harmful microbes such as bacteria and fungi. Under the FDA Modernization Act of 1997, the FDA conducted a comprehensive review of the use of thimerosal in childhood vaccines. This review found no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions (Thimerosal and Vaccines | FDA).

In 1999, with input from the Public Health Service and other partners, FDA requested all vaccine manufacturers for plans to remove thimerosal from vaccines. This was taken as a precautionary step, not due to evidence of harm, to reduce an infant's overall exposure to mercury, given that other environmental sources of mercury were challenging to eliminate.

NY Times

LAC recommendations:

- LAC DPH urges provider to follow ACIP recommendation for routine annual influenza vaccination of all persons aged 6 months and older who do not have contraindications.
- However, in contrast to the preponderance of scientific evidence, ACIP also voted that only influenza vaccines in single dose formulations that are free of thimerosal be used.
- Per California law, providers are prohibited administering mercury-containing vaccines to pregnant women or to children <3 years. All routine vaccines are available in formulations that meet the law. (Laws and Regulations, CA HSC 124172).
- However, for children over the age of 3 and non-pregnant adults, LAC DPH recommends that thimerosal products can be used, especially in situations when not using these products may lead to delays in vaccination or missed opportunities to vaccinate. There is no new scientific evidence warranting a change in recommendations for thimerosal-containing flu vaccines.

Other areas to watch:

- ACIP announced 2 new working groups to re-evaluate all childhood immunizations
  - Cumulative effect of childhood immunizations
  - Examine vaccines that have been in use for 7 years (specifically calling out the "evidence for" MMRV under 4 years and newborn Hep B doses)
  - Other workgroups have been put on hold, unsure of next meetings
  - Maybe another ACIP meeting August/September where COVID-19 votes may occur?

Questions