



Shot Topics:

What's New in Vaccines for 2024-2025

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Disclosure Statement

Amanda Applegate has/had a financial interest with Sunflower Health Plan and the relationship has been mitigated through peer review of this presentation. There are no relevant financial relationships with ACPE defined commercial interests for anyone else in control of the content of the activity.

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- 1. Describe current ACIP recommendations for routine and seasonal immunizations, including pneumococcal, RSV, and meningococcal vaccinations.
- 2. Identify common mistakes in storage and handling of immunizations.
- Recognize best practices for documentation, reporting, and referral strategies to support immunization services.

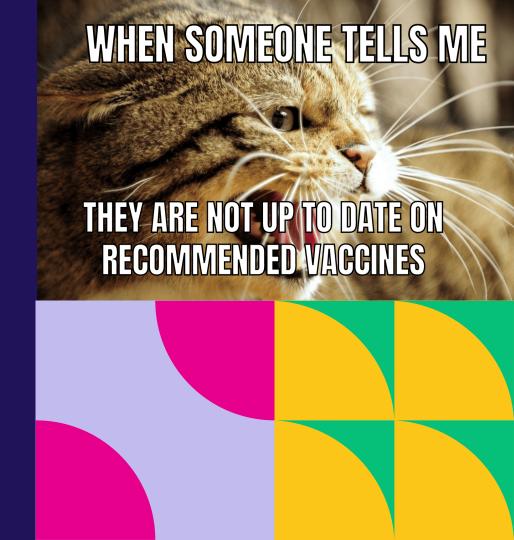
ThoughtSpot

Speaker



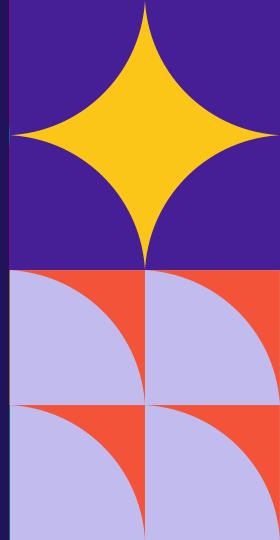
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- Clinical Updates
- Storage and Handling
- Resources



Legal Notes



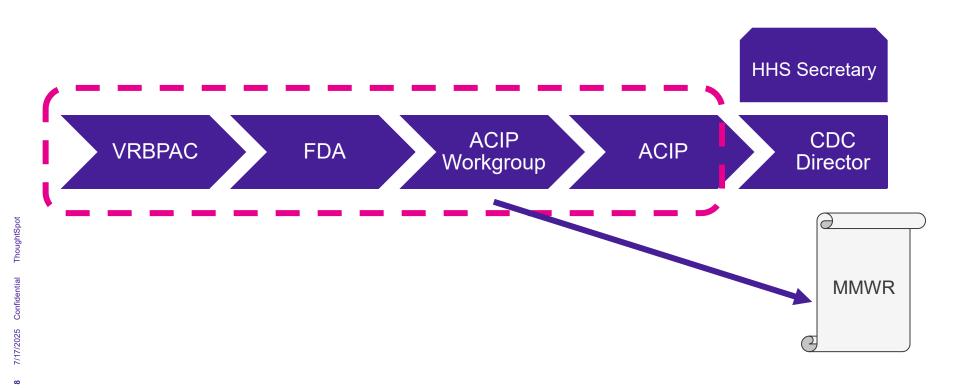


Public Readiness and Emergency Preparedness (PREP) Act

- 12th Amendment, effective through December 31, 2029
 - Pharmacists, pharmacy interns, and qualified pharmacy technicians
 - Patients 3 years and older
 - COVID & influenza only
 - Tests & vaccinations

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. Vaccination must be ordered and administered according to CDC's/ACIP's COVID-19 vaccine recommendation(s)

United States Vaccine Approval Process



VRBPAC - Vaccines and Related Biological Products Advisory Committee; HHS – Health and Human Services; MMWR – Morbidity and Mortality Weekly https://www.cdc.gov/acip/downloads/Policies-Procedures-508 1.pdf

Centers for Disease Control and Prevention's Advisory Committee for Immunization Practices

- "Federal advisory committee that develops recommendations on the use of vaccines in the civilian population of the United States"
 - Voting members
 - Up to 19 medical professionals
 - 1 consumer representative knowledgeable about social/community aspects of immunization programs
 - 8 non-voting ex officio members from federal agencies
 - 31 liaison members representing professional societies

What's next?

- American Health Insurance Providers and the Alliance of Community Health Plans affirmed their commitment to covering this fall's vaccinations
- Does your state statute or statewide protocol require you to follow ACIP guidelines?
- Does your physician protocol allow for flexibility?

Consent form

Required documentation

- Date of administration
- Vaccine manufacturer
- Vaccine lot number
- Name and title of person who administered vaccine
- Address of the facility where permanent record resides
- Vaccine information statement (VIS)
 - VIS Date
 - Date VIS given to patient/parent/quardian

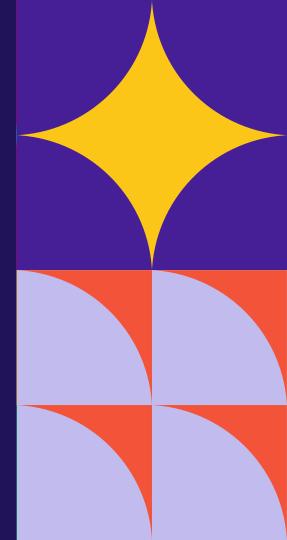
Dates of Current Vaccine Information Statements (VISs) as of May 29, 2025

Check your supply of VISs against this list. If you have outdated VISs, get current versions at www.immunize.org/vaccines/vis/

Adenovirus	1/8/20
Anthrax	1/8/20
COVID-19	1/31/25
Cholera	1/31/25
Dengue	1/31/25

Chikungunya





Chikungunya Vaccine Schedule



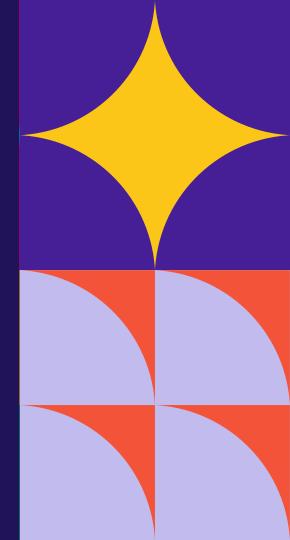
- Live attenuated (Ixchiq, Valneva) FDA approved November 2023 for 18 years of age and older
- Safety signal detected serious adverse events with Ixchiq in adults >60 years, use has been paused



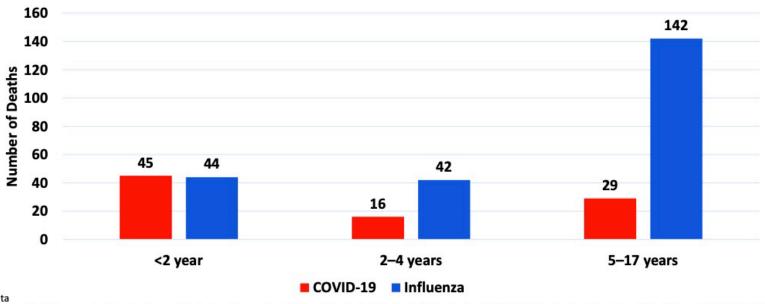
- Virus-like particle (Vimkuna, Bavarian Nordic) FDA approved
 February 2025 for 12 years of age and older
- ACIP recommended for people traveling to an area with a chikungunya outbreak and lab workers who might be exposed to the virus; consider for moving or extended travel to an area without risk
 - ACIP added Vimkuna April 2025

COVID-19





Total number of COVID-19- and Influenza-associated deaths^{1,2}, among ages 0–17 years in July 2024–June 2025, **United States**

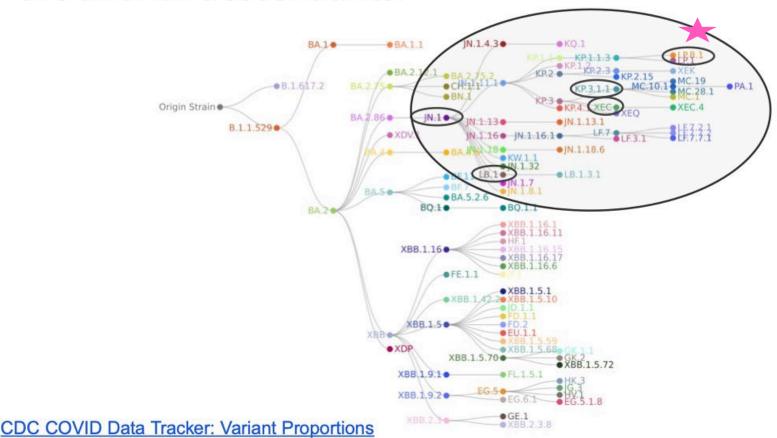


1. Provisional data

Note: Estimates of pediatric influenza deaths reported to CDC can be found here: https://www.cdc.gov/fluview/surveillance/2025-week-15.html. Estimates will vary due to differences in reporting methods and timeframes used.

^{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, provisional data for 2024 and provisional and partial data from 2025, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes influenza codes (J09-J11) or COVID-19 code (U07.1) as the underlying cause of death. http://wonder.cdc.gov/mcd-icd10provisional.html, accessed June 20, 2025

Viruses that have predominated since January 2025 are all JN.1 descendants.



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MacNeil, A. COVID-19 Epidemiology. ACIP Meeting. June 2025.

New vaccine option

- Low dose mRNA (mNexspike, Moderna) 10 μg/0.2mL
 - Approved for those who have previously received a COVID vaccine
 - 65 years and older
 - 12-64 years at high risk for severe COVID-19
 - Storage prefilled syringe
 - Frozen to expiration date
 - Fridge 90d
 - Room temp 24h

FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination

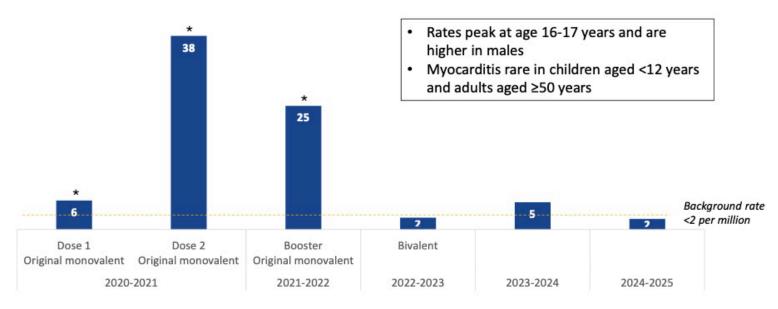
June 25, 2025

FDA Safety Communication

Purpose: To inform the public and healthcare providers that FDA has required and approved updates to the Prescribing Information for <u>Comirnaty</u> (COVID-19 Vaccine, mRNA) manufactured by Pfizer Inc. and <u>Spikevax</u> (COVID-19 Vaccine, mRNA) manufactured ModernaTX, Inc. to include new safety information about the risks of myocarditis and pericarditis following administration of mRNA COVID-19 vaccines.

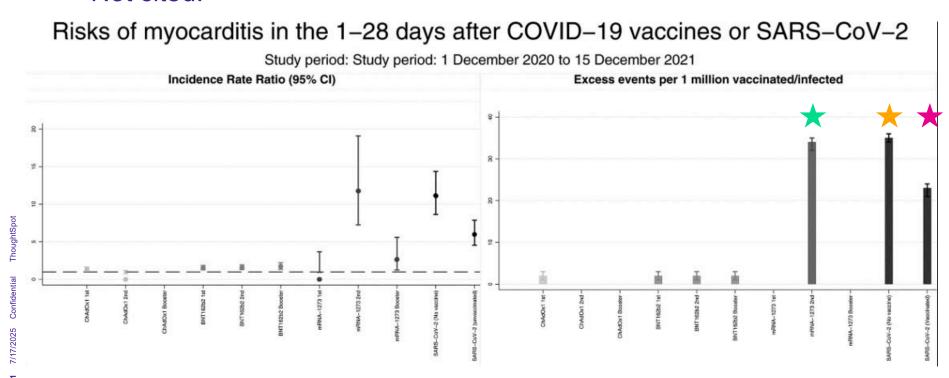
Myocarditis Following mRNA COVID-19 Vaccination Among People Ages 12–39 Years in the Vaccine Safety Datalink

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

Not cited:



Not cited:

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
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

COVID-19 Recommendations

 FDA – any new COVID vaccine approval must undergo placebocontrolled clinical trials focusing on symptomatic illness to earn a general recommendation

Announcement made that CDC has removed recommendation for COVID-19 vaccine for healthy children and pregnant women from routine schedules



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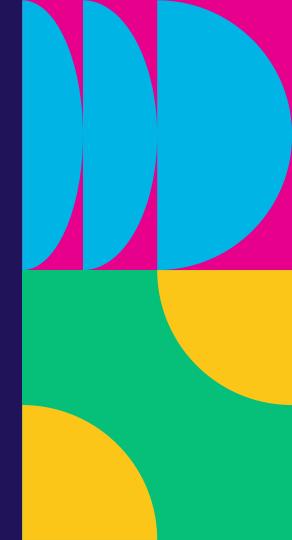
COVID-19 notes

ACIP COVID workgroup discussions only – NOT OFFICIAL POLICY

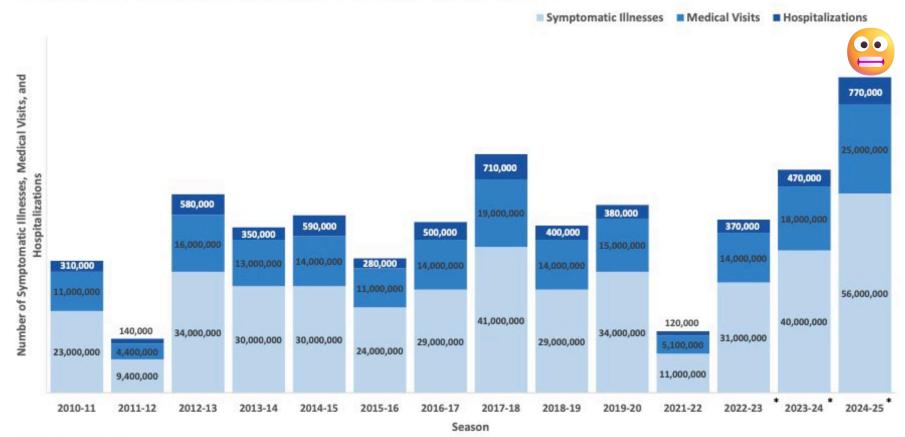
6-23 months	≥65 years
Universal recommendationAge-appropriate series	Universal recommendation2 doses
2-64 years	≥6 months, moderate to severe immunocompromise
 Anyone at high risk of severe COVID- 19, including during pregnancy Anyone with high risk of exposure Shared clinical decision making for everyone else 	Universal recommendation2 doses

Influenza





Influenza Disease Burden Varied by Season



*Preliminary Estimates

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Dugan V. Estimates of influenza burden and burden averted through vaccination. ACIP Meeting. June 2025. CDC. FluVaxView. Accessed June 7, 2025.

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New vaccine option

- Live attenuated influenza vaccine (FluMist, AstraZeneca) for home delivery and self/caregiver administration
 - Nasal spray flu vaccine
 - Indicated for ages 2-49 years



Disposal via mail-back

- Recombinant influenza vaccination (Flublok, Sanofi)
- FDA approved age range increase to 9 years and older March 2025

CHTYOUR FLUSHOT DOCCONETT

- ACIP affirmed existing recommendation that everyone aged 6 months and older should receive a flu shot
 - Preferential recommendation for high dose (Fluzone High Dose, Sanofi), adjuvanted (Fluad, Seqiris), or recombinant influenza (Flublok, Sanofi) vaccinations for all persons aged 65 years and older
 - Avoid vaccinating during July/August for most adults

- **Ethyl**mercury-based preservative
- Found in cosmetics, eye drops, disinfectants, and other medications
- Methylmercury found in fish





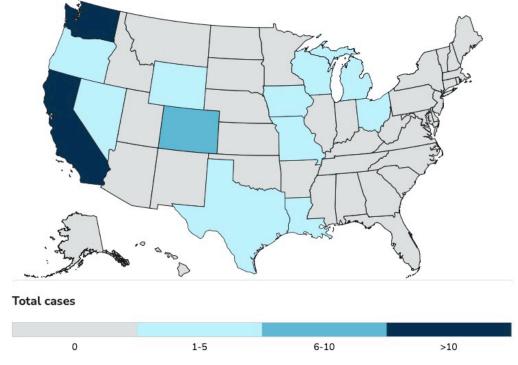
Multi-dose vials affected

Highly Pathogenic Avian Influenza (HPAI)

- No known person to person spread
- 70 total cases
- 7 probable cases
- 1 death

July 7, 2025

Confirmed Human Cases of HPAI since 2024

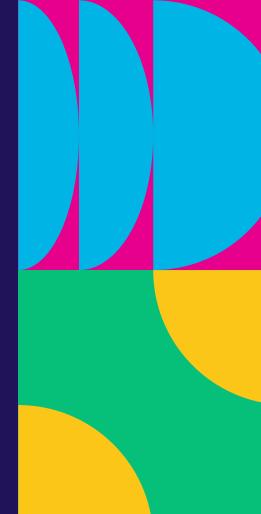


- 41 Dairy herds
- 24 Poultry farms

- 2 Other animal
- 3 Unknown source

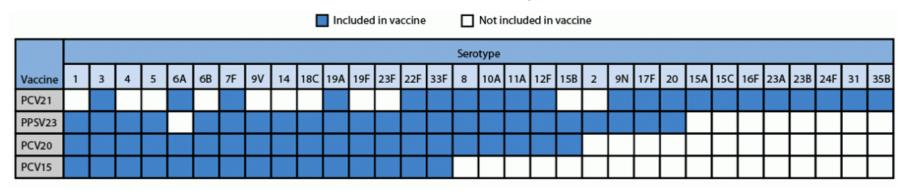
Invasive pneumococcal disease (IPD)





Invasive pneumococcal disease

- ACIP recommends a single dose of any PCV vaccine for all PCVnaïve adults aged ≥50 years
- 32-54% of adults aged 50-64 years had ≥1 qualifying risk
- 37% of adults aged 50-64 years with a risk were vaccinated
- IPD rates in black adults peak at 55-59 years



- Consider PCV20 or PCV15 + PPSV23 in areas where serotype 4 causes ≥30% of IPD cases or in specific underlying conditions:
- Alaska
- Colorado
- **Navajo Nation**
- New Mexico

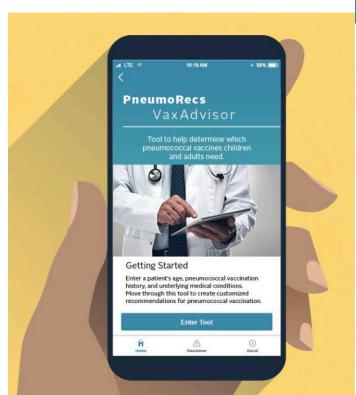
- Oregon
- Alcoholism
- Chronic lung disease

Homelessness

Injection drug use

Cigarette smoking

PneumoRecs VaxAdvisor



PneumoRecs VaxAdvisor PneumoRecs VaxAdvisor **Patient Characteristics** Age **Patient Characteristics** 19 through 49 years PCV15, PCV20, or PCV21 Age No prior doses ≥50 years Risk Factors PCV15, PCV20, or PCV21 Yes No prior doses PPSV23 PPSV23 Has received prior doses Has received prior doses PCV13 PCV13 No prior doses No prior doses Recommendation

Give one dose of PCV15, PCV20, or PCV21 at least 1 year after their last dose of PPSV23. Regardless of which vaccine used (PCV15, PCV20, or PCV21), their pneumococcal vaccinations are complete

Recommendation

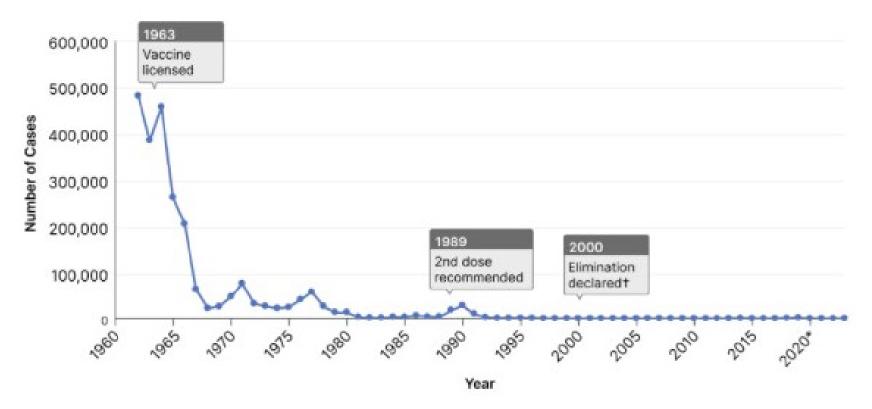
Give one dose of PCV15, PCV20, or PCV21 at least 1 year after the last dose of PPSV23. Regardless of which vaccine is used (PCV15, PCV20, or PCV21), their pneumococcal vaccinations are complete.

Measles





Reported Measles Cases in the United States from 1962 – 2023*

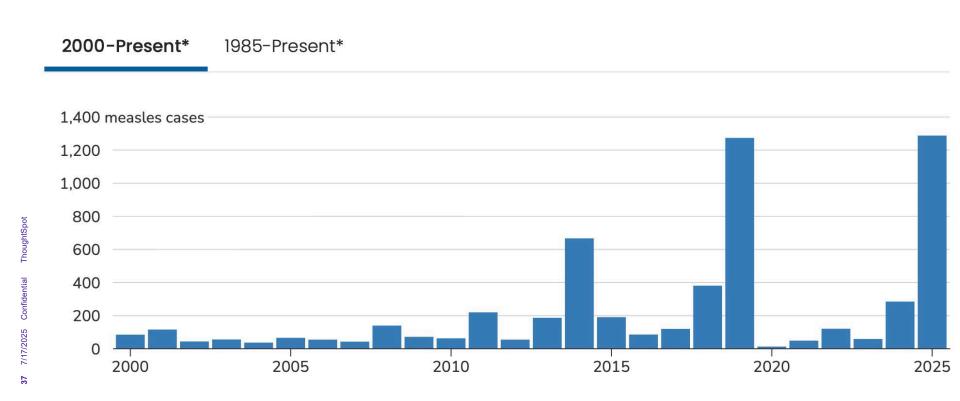


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https://www.cdc.gov/measles/data-research/index.html, https://www.cdc.gov/measles/about/history.html, https://www.idsociety.org/ID-topics/infectious-disease/measles/know-the-facts

Yearly measles cases

as of July 8, 2025



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Total cases: 285 Hospitalizations: 114 (40%)

Age

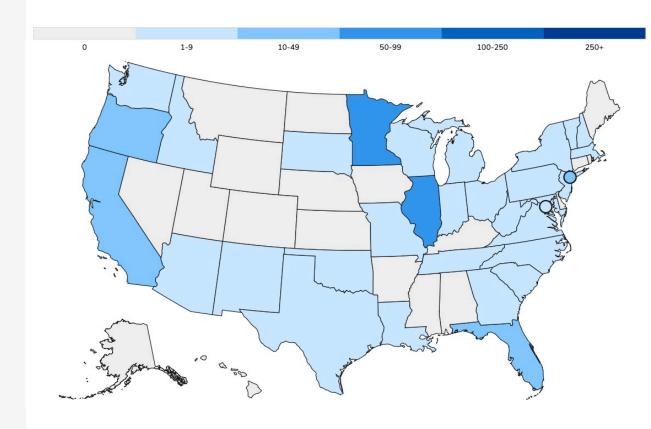
<5 years: 120 (42%) 5-19 years: 88 (31%) ≥20 years: 77 (27%)

Vaccination Status

Unvaccinated or unknown: 89%

One MMR dose: 7% Two MMR doses: 4%

US Measles Cases 2024



Total cases: 1288 Hospitalizations:

162 (13%)

Deaths: 3

Age

<5 years: 368 (29%)

5-19 years: 469 (36%)

≥20 years: 439 (34%)

Vaccination Status

Unvaccinated or

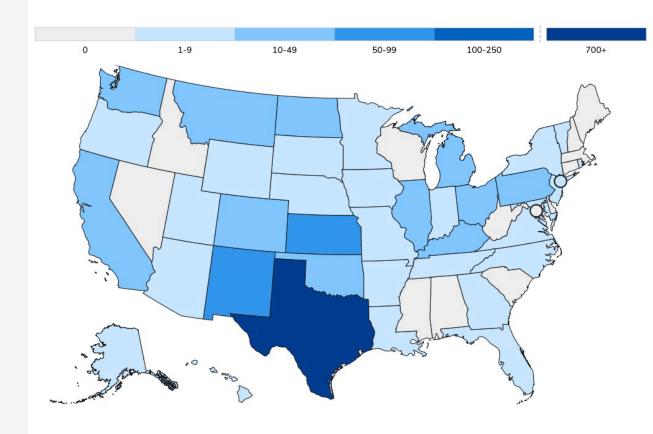
unknown: 92%

One MMR dose: 4%

Two MMR doses: 4%

July 7, 2025

US Measles Cases 2025



V

What is measles (rubeola)?

- Highly contagious airborne virus causing severe flu-like illness with a rash
- Complications occur in 3 in 10 patients
 - 1 in 20 pneumonia
 - 1 in 1000 encephalitis causing deafness and intellectual disability
 - 3 in 1000 death







- Day 10-14 Prodrome
 - 3 C's cough, coryza, conjunctivitis
 - Fever 103°-105°
 - Koplik spots on mucous membranes

Contagious 4 days before rash and 4 days after rash appears

- **Days 14-20 Rash**
 - Head → neck → trunk → limbs
- Day 21 2-3 years Post measles
 - Immune amnesia

Admin subQ or IM

≥12 months

room temp

Vaccine frozen.

diluent fridge or

Contains gelatin

MMRII (Merck)

Live

0.5 mL

ProQuad-MMRV (Merck)

- Live
- 0.5 mL
- Admin subQ or IM
- 12 mo 12 years
- Vaccine frozen, diluent fridge or room temp
- Contains gelatin

Priorix (GSK)

- Live
- 0.5 mL
- Admin subQ
- ≥12 months
- Vaccine refrigerated, diluent fridge or room temp

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Routine

Measles
Vaccination
Recommendations

Children

- 2 doses MMR or MMRV recommended for all children
- First dose at 12-15 months
- Second dose at 4-6 years (before school)

Adults

- One dose is recommended for all adults ≥18 years if no previous evidence of immunization or immunity
- Two doses 28 days apart are recommended for adults working in healthcare or attending college

Children

- Early dose at 6-11 months
- Subsequent dose at 12-15 months
- Final dose at 4-6 years (before school)
- Children >12 months with no history of MMR vaccine should receive one dose immediately then another dose after 28 days

Teens & Adults

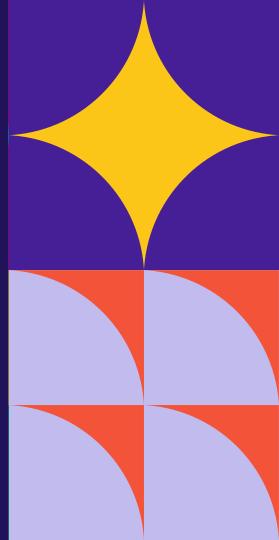
- One dose is recommended for all who have received one previous dose of any MMR vaccine
- Two doses 28 days apart are recommended for all with no history of vaccination

Outbreak

Measles Vaccination Guidance

Bacterial meningitis





Meningococcal Vaccine Schedule

- **MenACWY** recommended for all healthy persons aged 11-18 years
 - Single dose at 11-12 years
 - Booster dose at 16 years
- **MenB** recommended for healthy persons 16-23 years based on shared clinical decision making
 - 2 dose series



- MenABCWY (Penbraya, Pfizer) FDA approved October 2023
- MenABCWY (Penmenvy, GSK) FDA approved February 2025
- ACIP recommended for people aged 10-25 years who are receiving MenACWY and MenB vaccines at the same visit
- ACIP added Penmenvy April 2025

- Use same manufacturer for second MenB vaccine when due
 - Penbraya → Trumenba
 - Penmenvy → Bexsero, 6 months later

Respiratory syncytial virus (RSV)



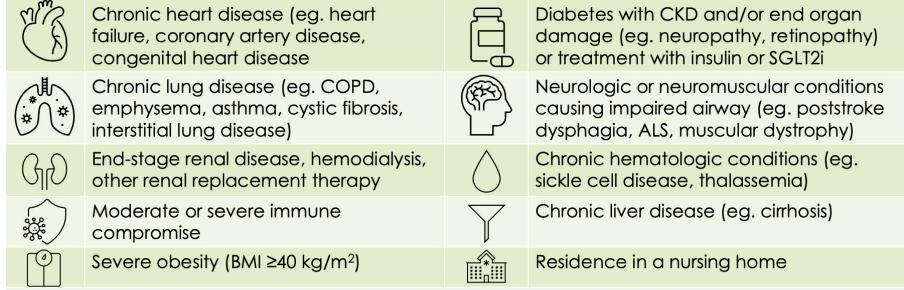


Adults aged 50-59 years at increased risk of severe RSV disease should receive a single dose of RSV vaccine

Recombinant protein (Arexvy, GSK)	Recombinant protein (Abrysvo, Pfizer)	mRNA (mRESVIA, Moderna)
FDA approved for 50 years and older	FDA approved for 18 years and older	FDA approved for 18 years and older

mere

Increased risk for severe RSV – Older Adults



Other chronic medical conditions or risk factors that a healthcare provider determines would increase the risk for severe disease (eg. frailty, concern for undiagnosed chronic conditions, residency in a remote or rural community where transportation of patients for escalation of medical care is challenging)

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New RSV Antibody Option - Infants

- Nirsevimab (Beyfortus, Pfizer) FDA approved July 2023
 - Recommended for infants <8 months who are born during or entering their first RSV season (October-March) if there is not evidence of vaccination during pregnancy
- Recommended for children aged 8-19 months who are at increased risk and entering their second RSV season
- Clesrovimab (Enflonsia, Merck) FDA approved June 2025
- Recommended for infants <8 months who are born during or entering their first RSV season (fall through spring) if there is not evidence of vaccination during pregnancy

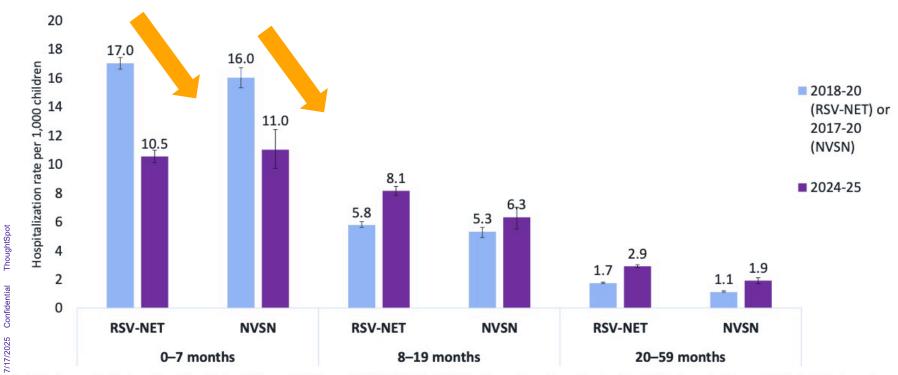
Summary of RSV prevention product effectiveness (PE) among infants in their first RSV season, 2024–2025

Outcome	Product	CDC Network	Product Eff	icacy*/Effectiveness (95% CI)
RSV-associated <u>ED visit</u>	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 <u>Intensive Care</u> <u>Unit (ICU) admission</u>	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

Cumulative adjusted RSV-associated hospitalization rates in 2024–25 were compared to seasons before product introduction by age group

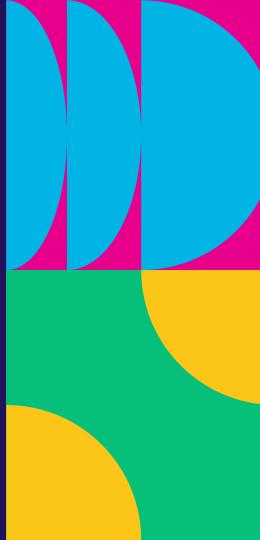




Bar labels indicate cumulative laboratory-confirmed RSV-associated hospitalizations per 1,000 children as of April 30 (RSV-NET) or March 31 (NVSN) each season. Rates use U.S. population denominators. RSV-NET rates are adjusted to account for RSV underdetection because of sets in practices and test sensitivity. NVSN rates are adjusted to account for weeks with <7 days of surveillance, the proportion of eligible children not enrolled, sensitivity of respiratory syncytial virus reverse-transcription polymerase chain reaction testing compared to serology, and each site's estimated market share of acute respiratory illness hospitalizations by age. (95% CI).

Storage and Handling





Emergency Response

Keep printed storage and handling document physically attached to the vaccine fridge

- Emergency contact(s)
- Plan (and backup plan!) for where the fridge contents go



Off-Site Transport



Emergency Transport

Manufacturer shipping containers, food coolers



Planned Transport

Purpose-built vaccine cooler

Routine Storage

- Purpose-built where possible
- Accurate thermometer
- Airflow (in & out!)
- Drugs/vaccine only
- Protect from light

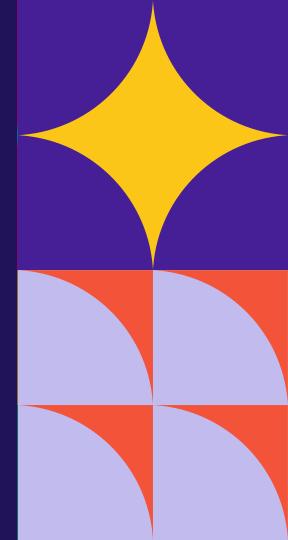






Immunization Resources





Immunization Neighborhood



Collaboration

Coordination

Communication

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Patient Resources

The Meg Foundation

- Decreasing pain & anxiety for painful procedures in children
- Poke Plans by age
- SuperMeg Poke Planner app



Pokes are a problem.



What's Buzzy?

Buzzy's vibrations block the pain signal so you don't have to feel the poke!



What's numbing cream?

It's a cream that you put on 30-60 minutes before the poke that numbs your skin!



What's Shotblocker?

Shotblocker is a plastic device with little "nubs" that distract your nerves. Your brain feels the nubs, but not the poke!

Does mRNA Alter DNA?

By Heather Simpson, Back to the Vax

VACCINE FEARS

OVERTURNED

BY FACTS



- Webinar Series

One of the biggest rumors floating around about the mRNA inside of the Moderna

and Pfizer COVI surface, this see can enter a cell seems like it co Were COVID-19 Vaccines Rushed?

Nope, it can't

What exactly is for protein proc

There is a difference between something be rushed and something being prioritized and expedited. The word "rushed" implies steps missed. Say you are at a restaurant and you cheeseburger.

Somehow, your cheeseburger was forgotte the kitchen made the rest of your table's or ensues and they quickly throw your order to their food at the came time Vallact your hi

Do Vaccines Cause Autism?

By Lydia Greene, Back to the Vax

Short Answer: No. Wow, that was easy. (kidding).

Long Answer: Here is how I realized that vaccines do not cause autism from the lens of a former anti-vax parent. I have 3 children, and I stopped vaccinating when my oldest was just 4 months old. My next 2 children were completely unvaccinated. Being in the anti-vax crowd led me to have the wrong idea of what autism is. Parents in

Thank you!

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