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NCPA 2025 ANNUAL CONVENTION



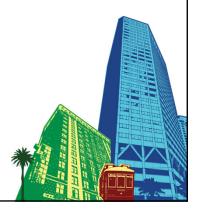
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# Navigating the Latest Vaccine Recommendations



NCPA 2025 Annual Convention and Expo



## Speaker



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Director of Practice Development
Kansas Pharmacists Association & CPESN
Kansas



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3

#### **Disclosure Statement**

Amanda Applegate has 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.





#### Pharmacist and Technician Learning Objectives

- Summarize the process for vaccine recommendations in the United States.
- Describe the impact of vaccine-preventable disease outbreaks in the United States.
- Discuss recent updates to vaccine recommendations that influence the delivery of pharmacy-based immunization services.
- Apply current Centers for Disease Control and Prevention and Advisory Committee on Immunization Practices immunization schedules and recommendations to patient cases.

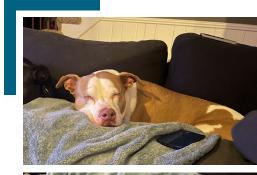


5

## Wake up!

Does your state require you to immunize per CDC/ACIP guidelines?

Are you using the PREP Act to extend your vaccine types/age range?







## Wake up!

What types of vaccines does your pharmacy offer?

- Routine adult vaccines
- Childhood vaccines
- Travel vaccines
- Respiratory vaccines only







8



# 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)



https://public-inspection.federalregister.gov/2024-29108.pdf FDA – Food and Drug Administration, CDC – Centers for Disease Control and Prevention, ACIP – Advisory

10

# 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



https://www.cdc.gov/acip/grade

#### GRADE

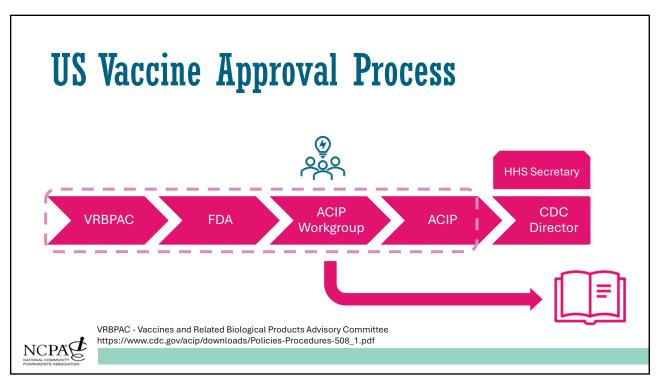
Standardized process for developing ACIP recommendations for transparency, consistency, and communications

- · Policy question defined
  - Population, Intervention, Comparison, Outcomes (PICO)
- Benefits and harms critical to policy decision defined
- Systematic review of evidence for efficacy and safety
  - Published and unpublished



https://www.cdc.gov/acip/downloads/Policies-Procedures-508\_1.pdf

12



#### 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 require you to follow specific recommendations?
- Does your statewide/physician protocol allow for flexibility?



https://www.cdc.gov/acip/downloads/Policies-Procedures-508\_1.pdf

14

#### Protocol check: Can I give this vaccine??

Jamie, a 28 year old female, wants a COVID vaccination. She has no chronic conditions, but she is scared of long COVID.

"Certified immunizers should administer vaccinations that are FDA approved and that are recommended by the CDC/ACIP."





#### Protocol check: Can I give this vaccine??

Jamie, a 28 year old female, wants a COVID vaccination. She has no chronic conditions, but she is scared of long COVID.



"Vaccinate according to indications and contraindications recommended in current guidelines from ACIP/CDC, or as authorized by the FDA, and/or recommended by other evidence-based authorities."



16

#### Other Authorities

#### **Professional Associations**

- American Academy of Pediatrics (AAP)
- American College of Obstetrics and Gynecology (ACOG)
- American Cancer Society (ACS)

#### Professional Guidelines

American
 Diabetes
 Association
 Standards of
 Care

#### State Issued Guidance

- West Coast Health Alliance
- Statewide standing orders/ protocols

#### New Organizations

 Vaccine Integrity Project





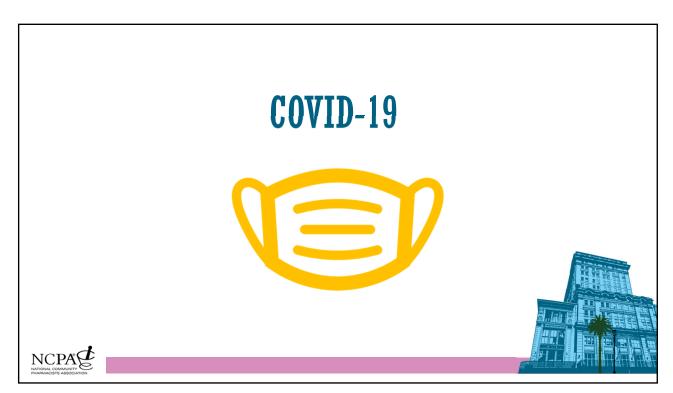


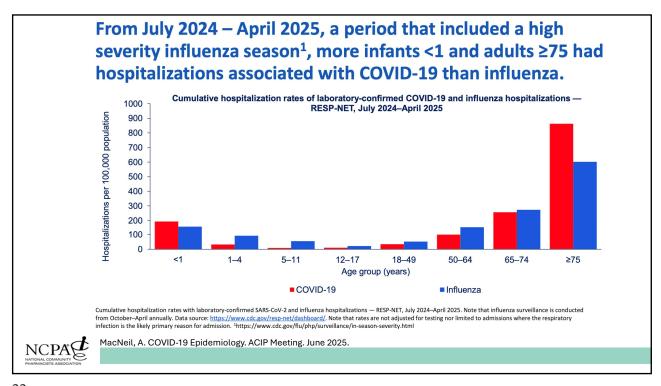
## Chikungunya Vaccine

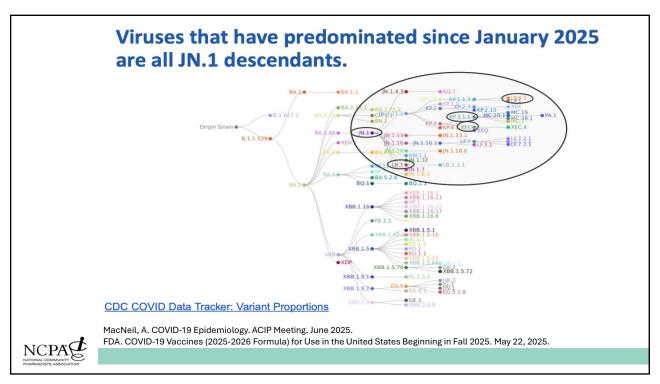
- Live attenuated (Ixchiq, Valneva) FDA approved November 2023 for 18 years of age and older
  - Safety signal detected serious adverse events in adults aged 60 years and older
  - Use paused in affected population
- Virus-like particle (Vimkuna, Bavarian Nordic) FDA approved February 2025 for 12 years 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



20







#### New vaccine

- Low dose mRNA (mNexspike, Moderna) 10 µg/0.2mL
  - FDA 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: 90 days
  - · Room temp: 24 hours





FDA. Package Insert – mNexspike. https://www.fda.gov/media/186738/download?attachment Moderna. Relative vaccine efficacy against COVID-19. https://products.modernatx.com/mnexspikepro/efficacy

24

## **COVID-19 Safety Notes**

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

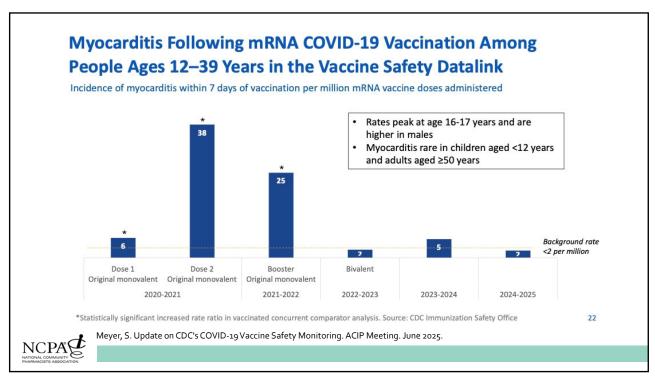
June 25, 2025

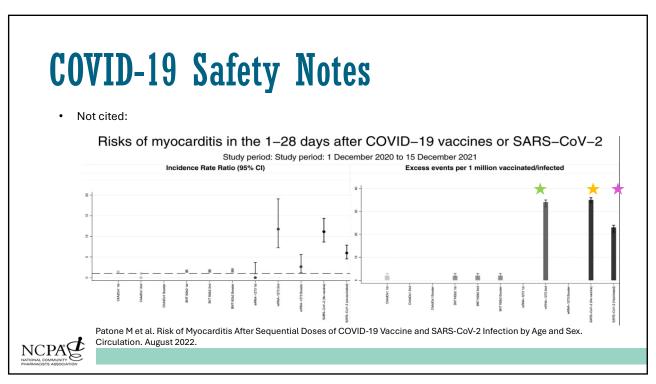
**FDA Safety Communication** 

Purpose: To inform the public and healthcare providers that FDA has required and approved updates to the Prescribing Information for Comirnaty (COVID-19 Vaccine, mRNA) manufactured by Pfizer Inc. and Spikevax (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.



FDA. FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination. June 25, 2025.





## **COVID-19 Safety Notes**

#### · Not cited:

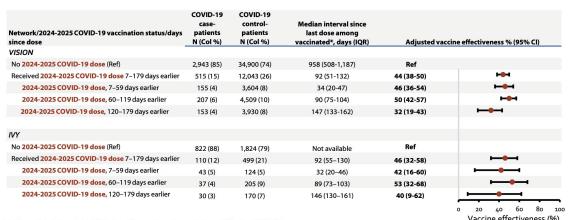
	Postvaccine myocarditis (n = 558)		Post-COVID-19 myocarditis (n = 298)		Conventional myocarditis (n = 3779)	
Outcome	No. of events (%)	Weighted hazard ratio <sup>a</sup>	No. of events (%)	Weighted hazard ratio <sup>a</sup>	No. of events (%)	Weighted hazard ratio <sup>a</sup>
Rehospitalization for myopericarditis	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 <sup>b</sup>	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 <sup>c</sup>	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 <sup>c</sup>	75 (13.4)	0.64 (0.48-0.85)	76 (25.5)	1.03 (0.75-1.40)	874 (23.1)	1



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;332(16):1367–1377. doi:10.1001/jama.2024.16380

28

Effectiveness of 2024–2025 COVID-19 vaccination against COVID-19—associated hospitalization among immunocompetent adults aged ≥65 years — VISION and IVY Networks
September 2024 – May 2025



 $Updated\ from: Link-Gelles,\ et\ al.\ MMWR: \underline{https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a1.htm}$ 



MacNeil, A. COVID-19 vaccine effectiveness update. ACIP. September 2025.

## Effectiveness of 2024–2025 COVID-19 vaccination against COVID-19–associated critical illness among immunocompetent adults aged ≥65 years — VISION and IVY Networks September 2024 – May 2025

2024-2025 COVID-19 vaccination status/days since dose	COVID-19 case- patients N (Col %)	COVID-19 control- patients N (Col %)	Median interval since last dose among vaccinated*, days (IQR)	Adjusted va	accine effectiveness % (95% CI)
VISION					
No 2024-2025 COVID-19 dose (Ref)	558 (85)	34,900 (74)	961 (510-1,189)	Ref	
Received 2024-2025 COVID-19 dose 7–179 days earlier	97 (15)	12,043 (26)	92 (51-132)	45 (31-56)	
2024-2025 COVID-19 dose, 7–59 days earlier	28 (4)	3,604 (8)	34 (20-47)	46 (21-64)	
2024-2025 COVID-19 dose, 60-119 days earlier	44 (7)	4,509 (10)	90 (75-104)	45 (25-60)	
2024-2025 COVID-19 dose, 120-179 days earlier	25 (4)	3,930 (8)	147 (133-162)	43 (13-62)	
IVY					
Acute respiratory failure					
No 2024-2025 COVID-19 dose (Ref)	158 (88)	1,817 (78)	Not available	Ref	
Received 2024-2025 COVID-19 dose 7-179 days earlier	21 (12)	498 (22)	96 (59-131)	44 (11-67)	
ICU admission or death					
No 2024-2025 COVID-19 dose (Ref)	141 (91)	1,824 (79)	Not available	Ref	
Received 2024-2025 COVID-19 dose 7–179 days earlier	14 (9)	499 (21)	96 (60-133)	56 (23-76)	
Invasive mechanical ventilation or death					
No 2024-2025 COVID-19 dose (Ref)	74 (94)	1,824 (79)	Not available	Ref	
Received 2024-2025 COVID-19 dose 7-179 days earlier	5 (6)	499 (21)	97 (60-133)	70 (35-89)	

Based on methods in: Link-Gelles, et al. MMWR: https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a1.htm



MacNeil, A. COVID-19 vaccine effectiveness update. ACIP. September 2025.

30

#### **COVID-19 Recommendations: ACIP**

- Adults 65 years and older: Vaccinate based on individualbased decision making\*
- Individuals 6 months to 64 years: Vaccinate based on individual-based decision making
  - Emphasis that risk-benefit of vaccination is most favorable for individuals who are at increased risk for severe COVID-19 disease
- Individual-based decision making = shared clinical decision making
  - Pharmacists allowed to vaccinate per shared clinical decision making



CDC Newsroom. October 6, 2025

#### COVID-19 Recommendations: FDA

- Approved for use in individuals aged 65 years and older
- Approved for use in individuals in the following age groups with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19

SPIKEVAX	Comirnaty	mNEXSPIKE	Nuvaxovid
(Moderna)	(Pfizer)	(Moderna)	(Novavax)
6 months – 64 years	5 – 64 years	12 – 64 years	12 – 64 years



FDA Package Inserts

32

#### **COVID-19 Recommendations: AAP**

- All infants and children aged 6-23 months are at high risk and should receive the 2026-2026 COVID-19 vaccine
  - Initial series or current season dose
- Children 6 months 18 years who are immunocompromised should receive 2+ doses of the 2025-2026 COVID-19 vaccine
- Children and adolescents aged 2-18 years should receive a single dose of the 2026-2026 COVID-19 vaccine





American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents: Policy Statement. Pediatrics. 2025; doi: 10.1542/peds.2025-073924 -- Image: Microsoft stock image

## **COVID-19 Recommendations: ACOG**

 Continues to recommend the use of updated COVID-19 vaccines in individuals contemplating pregnancy and in pregnant, recently pregnant, and lactating individuals.

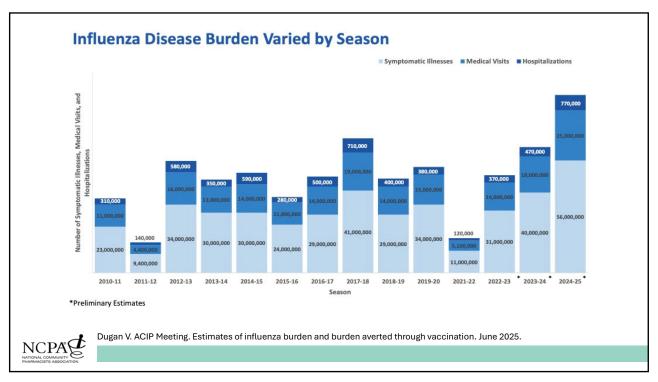


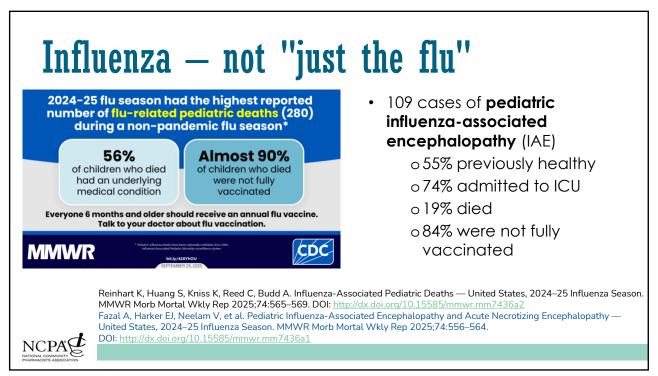


American College of Obstetrics and Gynecology. COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care. Updated September 2025.

34







## 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

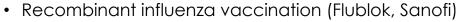


AztraZeneca. FluMist Home Delivery. https://www.flumist.com/ordering-using-at-home

38

#### Influenza Notes





- FDA approved age range increase to 9 years and older March 2025
- 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



#### Influenza Notes

- ACIP voted to remove flu shots containing thimerosal from the recommendation
- What is thimerisol?
  - <u>Ethyl</u>mercury-based preservative to protect against contamination



- Found in cosmetics, eye drops, disinfectants, and other medications
- <u>Methyl</u>mercury environmental toxin
  - · Primarily found in fish and shellfish





40

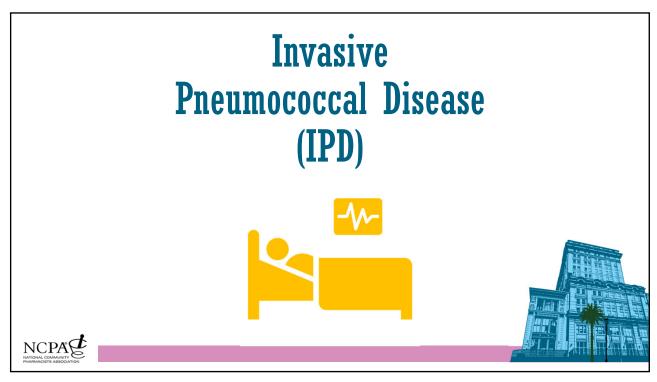
## Highly Pathogenic Avian Influenza (HPAI)

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



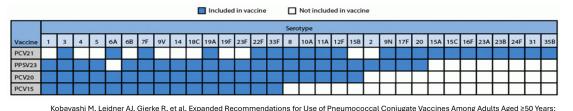
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CDC. H5 Bird Flu: Current Situation. https://www.cdc.gov/bird-flu/situation-summary/index.html?cove-tab=0



## Invasive pneumococcal disease

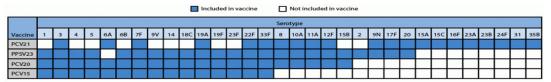
 ACIP recommends a single dose of any PCV vaccine for all PCVnaïve adults aged ≥50 years or when vaccination history is unknown



Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2025;74:1–8. DOI: http://dx.doi.org/10.15585/mmwr.mm7401a1.

NCPA PHARMACISTS ASSOCIATION

## Invasive pneumococcal disease



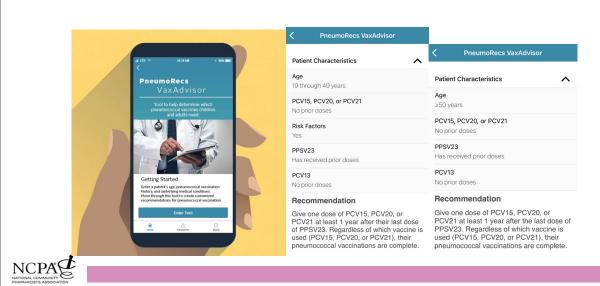
- Consider PCV20 or PCV15 + PPSV23 in areas where serotype 4 causes ≥30% of IPD cases or in specific underlying conditions
- Alaska
- Colorado
- Navajo Nation
- New Mexico
- Oregon
- Alcoholism
- Chronic lung disease
- Cigarette smoking
- Homelessness
- Injection drug use

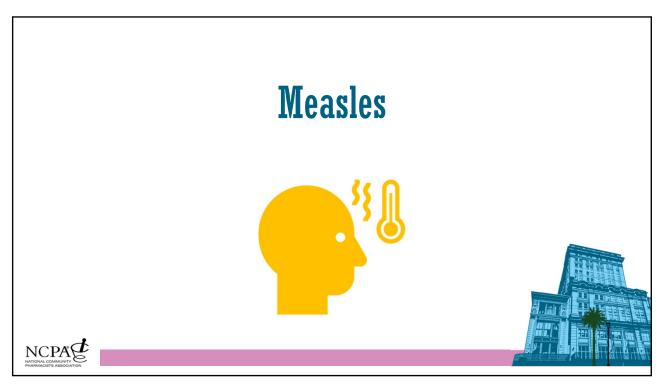


Kobayashi M, Leidner AJ, Gierke R, et al. Expanded Recommendations for Use of Pneumococcal Conjugate Vaccines Among Adults Aged ≥50 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2025;74:1–8. DOI: http://dx.doi.org/10.15585/mmwr.mm7401a1.

44

#### PneumoRecs VaxAdvisor





#### 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

https://www.cdc.gov/measles/hcp/communication-resources/consider-measles-infographic.html, https://www.idsociety.org/ID-topics/infectious-disease/measles/know-the-facts, https://www.who.int/news-room/fact-sheets/detail/measles



## **Approximate Timeline**

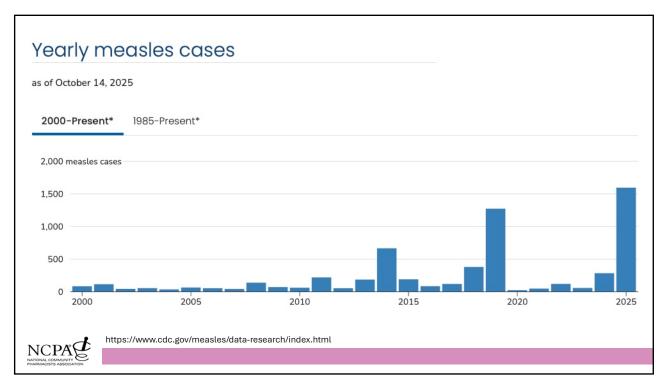
- · Day 0 Exposure
- Day 10-14 Prodrome
  - 3 C's cough, coryza, conjunctivitis
  - Fever 103°-105°
  - · Koplik spots on mucous membranes
- Days 14-20 Rash
  - Head → neck → trunk → limbs

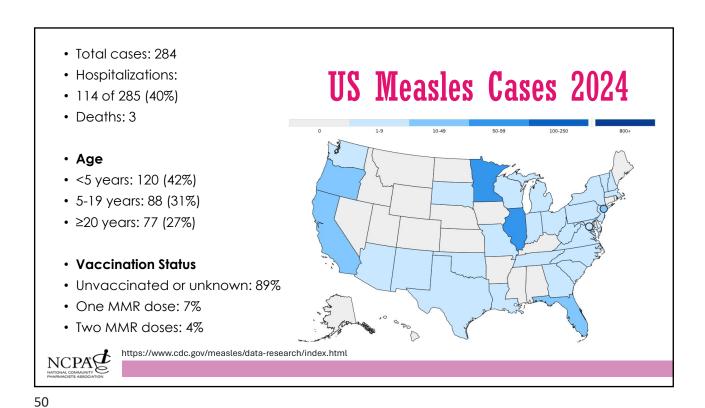
Contagious 4 days before rash and 4 days after rash appears

- Day 21 2-3 years Post measles
  - Immune amnesia



CDC. Epidemiology and Prevention of Vaccine Preventable Diseases – 14th Edition, https://www.who.int/news-room/fact-sheets/detail/measles https://asm.org/articles/2019/may/measles-and-immune-amnesia; Mina MJ, et al. Measles virus infection diminishes preexisting antibodies that offer protection from other pathogens. Science 2019;366:599-606.





Total cases: 1227
 Hospitalizations:

 148 (12%)
 Deaths: 3

 Age

 <5 years: 355 (29%)</li>
 5-19 years: 455 (37%)
 ≥ 20 years: 404 (33%)

 Vaccination Status

 Unvaccinated or unknown: 95%
 One MMR dose: 2%
 Two MMR doses: 3%

https://www.cdc.gov/measles/data-research/index.html

#### **Outbreak Measles Vaccination Guidance**

#### 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 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



52

#### **Measles Vaccinations**

#### MMRII (Merck)

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

#### ProQuad MMRV (Merck)

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

#### Priorix (GSK)

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



FDA Package Inserts

#### ACIP MMR/MMRV Vaccination

#### Children

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

#### **Adults**

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



54

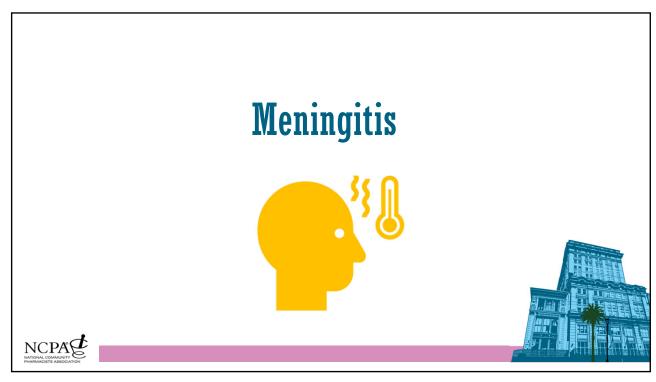
## ACIP MMR/MMRV Vaccination Safety Stats

- 1 in 3000 children (0.03%) experience a febrile seizure following the first dose of MMR vaccine
- 1 in 2300-2600 children (0.03-0.04%) experience a febrile seizure following the first dose of MMRV vaccine
- No increased risk for febrile seizure observed after MMRV vaccination in ages 4-6 years old

Baseline risk of febrile seizure following infection: 2-5%, peak incidence at 12-18mo

Feemster, K. Delay in measles vaccination associated with increased risk of post-vaccination seizures. Peds. Volume 164, Issue 3, 672-676.
McLean, H. et al. Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013: Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). June 2013.
Xixis KL, Samanta D, Smith T, et al. Febrile Seizure. [Updated 2024 Jan 19]. In: StatPearls Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-.





## 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



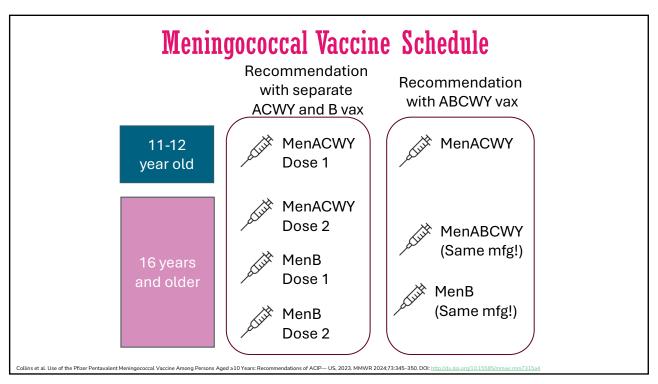


#### Meningococcal Vaccine Schedule

- 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



58





# RSV Vaccine Recommendations — Older Adults

 All adults aged ≥75 years and adults aged 50-74 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



ACIP Meeting. RSV – Older Adults. April 2025. FDA Package inserts – Arexvy, Abrysvo, mRESVIA. Accessed June 2025.

# Increased risk for severe RSV — Older Adults 60-74 years



Chronic heart disease (eg. heart failure, coronary artery disease, congenital heart disease



Chronic lung disease (eg. COPD, emphysema, asthma, cystic fibrosis, interstitial lung disease)



End-stage renal disease, hemodialysis, other renal replacement therapy



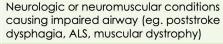
Moderate or severe immune compromise



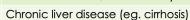
Severe obesity (BMI ≥40 kg/m²)



Diabetes with CKD and/or end organ damage (eg. neuropathy, retinopathy) or treatment with insulin or SGLT2i



Chronic hematologic conditions (eg. sickle cell disease, thalassemia)





. . .

Residence in a nursing home

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)



Britton A, Roper LE, Kotton CN, et al. Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep. ePub: 6 August 2024. DOI:

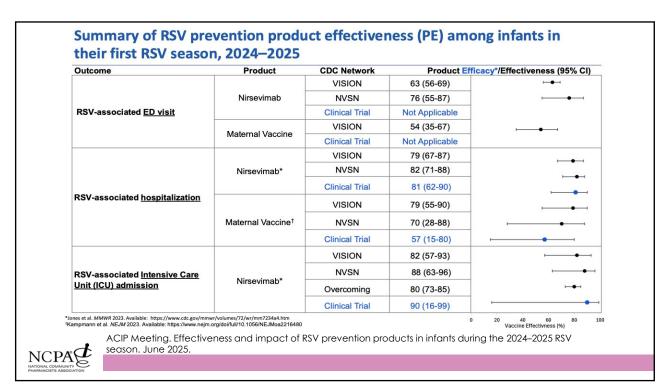
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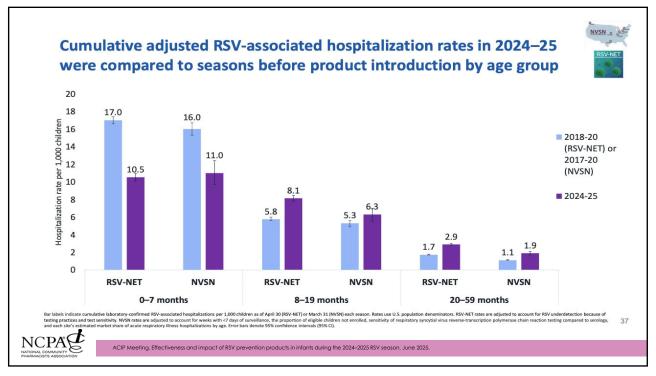
#### New RSV Antibody Option - Infants

- 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



https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html ACIP Meeting, June 2025.









#### **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!



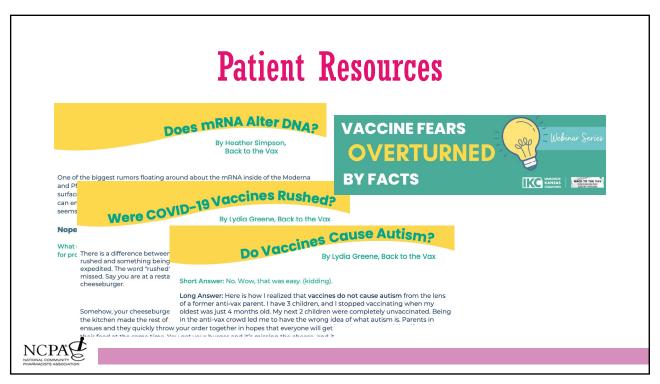
What's numbing cream?
It's a cream that you put on
30-60 minutes before the
poke that numbs your skin!



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

NCPA®

68





#### **Patient Case**

Mary – 67 year old woman walks into your pharmacy on October 24. You have flexible protocol language.

#### Chronic conditions:

- Seasonal allergies
- Hypertension
- Depression



## Patient Case

Richard - 70 year old man walks into your pharmacy on October 25. You have flexible protocol language.

#### Chronic conditions:

- Diabetes, treated with SGLT2i
- Prostate cancer, watch and wait









