

Outline

- ACIP
- Current Adult Immunizations: Recommendations and Evidence Flu, COVID-19, RSV, Pneumococcal, Zoster, HBV, HPV
- Evidence Gaps
- Future Opportunities
- Suggestions for uncertain times ...





Advisory Committee on Immunization Practices (ACIP)

- Develop US immunization recommendations and advise CDC Director
- Up to 20 voting members
 - 18 independent medical/public health experts
 - · 1 public representative
 - Minimum 20% designated minority representation
 - Overlapping 4-year terms
 - · All require approval by HHS Secretary
- Ex-Officio: 6 federal agency employees
- Liaison: 30 representatives of organizations with immunization expertise





www.cdc.gov/acip/downloads/Policies-Procedures-508_1.pdf www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management

ACIP Members: COI Requirements

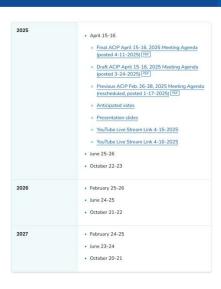
- No member/spouse/immediate family can be directly employed by vaccine manufacturer or its parent company
- Members cannot hold stock in any vaccine manufacturer or parent company in excess of OGE de minimus amounts;
 members agree that they/spouse/minor children will not purchase such stock during their tenure
- Members cannot be holders of or otherwise entitled to royalties or other compensation for a patent on a vaccine
 product or process, immunologic agent, adjuvant, or preservative that can be used for a vaccine that may come before
 ACIP during the anticipated term of appointment under consideration
- Members agree to resign any advisory or consulting roles, whether paid or unpaid, to a vaccine manufacturer (except
 participation in clinical trials or service on data monitoring boards) and to forego such consultation or membership on
 any vaccine manufacturer advisory committees (except participation in clinical trials or service on data monitoring
 boards) during tenure
- Members forego solicitation or acceptance of funds from vaccine manufacturers on behalf of themselves or others
- During ACIP tenure, members do not serve as paid litigation consultants or expert witnesses in litigation involving a
 vaccine manufacturer
- Members do not accept honoraria or travel reimbursement with a funding source from a vaccine manufacturer for attendance at scientific meetings, with the exception that they may receive travel reimbursement for CME presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer



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

ACIP Meetings

- 3 times/year: Announced 6-12 months in advance
- Generally requires 60-days notice in Federal Register
- Most meetings are open and include public comment
- · CDC Director has final decision
- Once CDC Director acts, MMWR publishes final recommendations





www.cdc.gov/acip/meetings/index.html www.cdc.gov/acip/index.html

Vaccines for Children (VFC) Program

- ACIP recommendations for VFC program have distinct process
- High priority placed on alignment between ACIP recommendations + VFC coverage
- Specific votes required for VFC program coverage







ACIP Solicits for New Members [Annually]

- Openings published on ACIP webpage and Federal Register
- Vetted by ACIP Executive Secretary, Secretariat, and Steering Committee
- CDC Director reviews and sends approved slate to HHS Secretary
- HHS Secretary nominates members [may or may not be on slate]
- ACIP appointed members are Special Government Employees and subject to all COI rules/regulations
- Candidate packets on slate members not selected are held for consideration for potential future vacancies ...



Apply for ACIP Membership

Access the online application for ACIP membership and learn about qualifications.



www.cdc.gov/acip/apply-for-membership/index.html www.cdc.gov/acip/downloads/Policies-Procedures-508_1.pdf

ACIP: Status and Policies

- February Meeting, April 15-16, 2025

 Meningococcal Pentavalent [And VFC] **VOTE, VFC VOTE**

VE and Self-administered nasal Influenza

• COVID-19 VE, Epi and Moderna next generation

 RSV Adult Expand indications to 50-59 at risk

 RSV Newborn New monoclonal for infants

 Chikungunya Disease, new VLP vaccine

 Pneumococcal Workgroup updates HPV Coverage, new data

Data on vaccine in 12-17 years Mpox

 Lyme Reconstitute workgroup Disease, CMV vaccine data CMV

Next scheduled meeting: June 25-26, 2025

VOTE

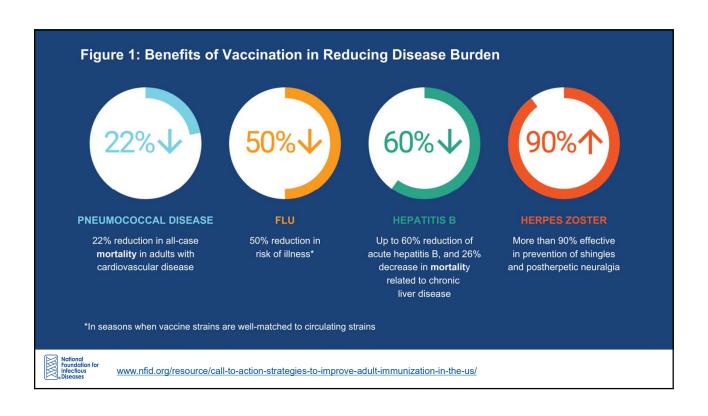
VOTE

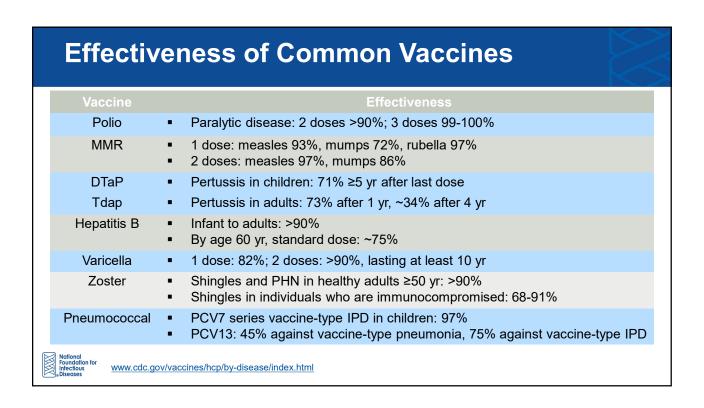
As of 5/8/2025: No word on whether these have been approved as public health policy by CDC Director (nor HHS leadership in absence of CDC Director) ...

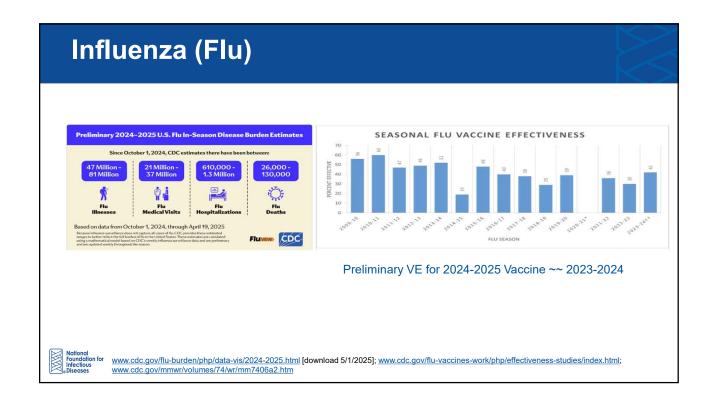


www.cdc.gov/acip/downloads/agendas/draft-posted-2025-03-24-508.pdf

Adult Vaccines and Vaccination







Flu

- Vaccine is key to prevention of severe disease > infection
 - 1 dose annually for all > 6 months [2 doses @ 1+ month: children <9 in 1st vaccination season only]
- Vaccine effectiveness generally 40-50% in adults, BUT varies by individual (timing, health status, circulating strains)
- Benefit > Zero (if unvaccinated)
- Why is flu vaccination so important?

Greatest benefit is reduction in risk for severe disease and serious related complications (hospitalization and death)



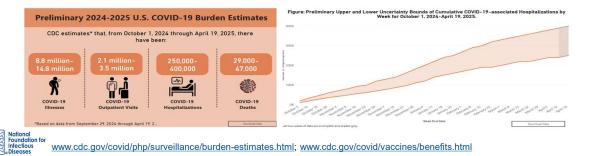
We are not vaccinating enough of the population!!



COVID-19

Hospitalization and death rates have declined year/year since 2021 \dots 2023-2024:

- 50% reduction in COVID-19 hospitalization in adults 65+
- 36% reduction in COVID-19 hospitalization in IC persons
- Vaccination during pregnancy reduced risk for COVID-19-related hospitalization by 54% in infants during 1st 3 months of life
- October 2022-April 2024: 1470 infants less than 6 months hospitalized with COVID-19



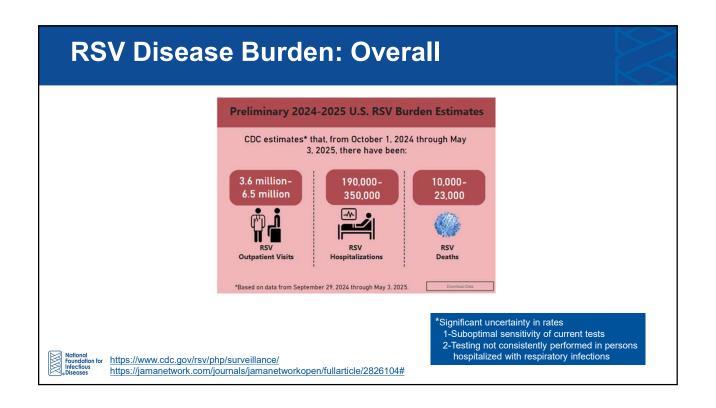
COVID-19

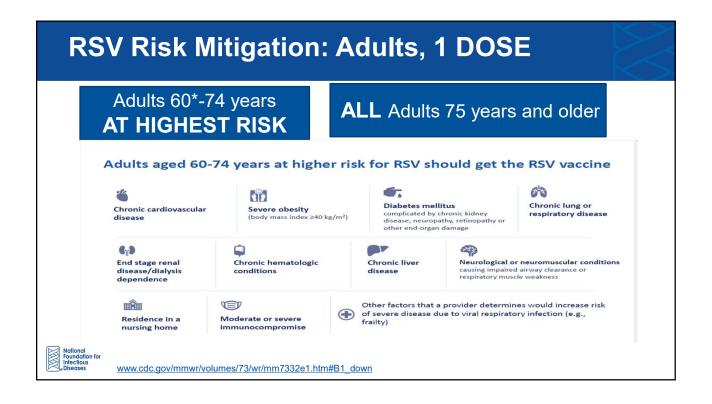
- Vaccine is THE key to:
 - · Reduction in severe disease [greater than reduction in infection]
 - Reduction in long-COVID risk [lots of data, ongoing challenge in defining long-COVID]
- Recommendation:
 - 2-3 doses mRNA vaccine (6 months-4 years)
 - 1 dose mRNA vaccine (4-11 years)
 - 1 dose any vaccine (12-64 years)
 - Vaccination during pregnancy (good for mom and baby)
 - · 2 doses in adults 65+
 - · 2 or more doses in immunocompromised





www.cdc.gov/covid/hcp/vaccine-considerations/overview.html





RSV Vaccines: Effectiveness and Safety

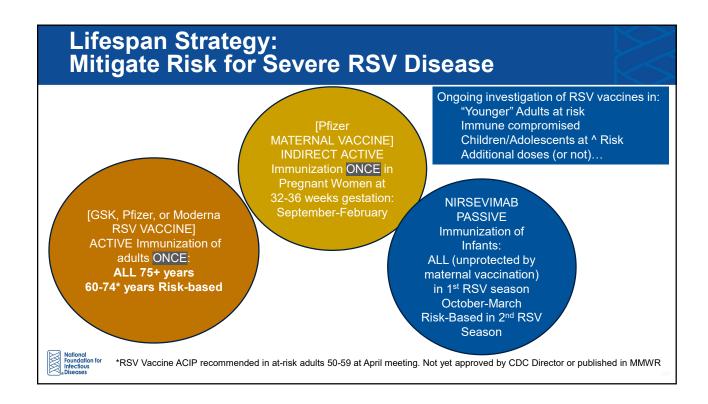
- Vaccine effectiveness [real world]
 - VISION Network: 28271 RSV hosp, 36521 ED visits in adults 60+ 10/23-3/24 77% VE against RSV-associated ED visits

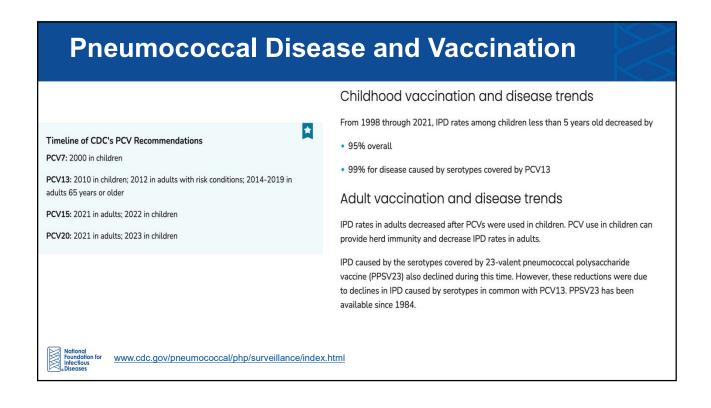
No IC: 80% VE vs. RSV hospital admit, 81% vs. RSV ICU admit/death/both IC: 73% VE vs. RSV hospital admit, 81%

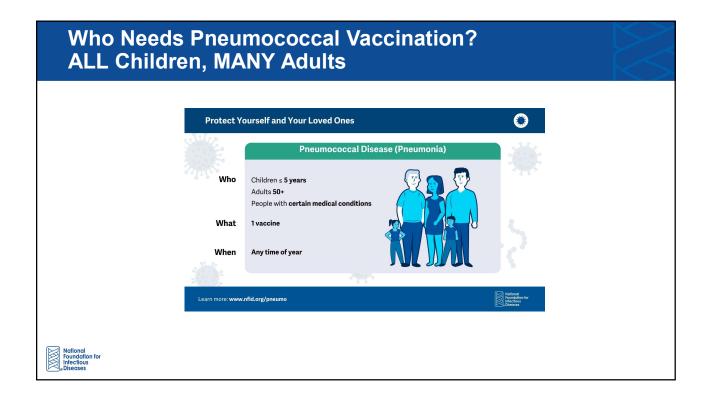
- VA: 146852 vaccinated v 582936 controls, median 75.9 years
 VE 78.1% RSV illness, 78.7% v. RSV ED/UC visits, 80.3% v. RSV Hospitalization
- Vaccine safety
 - V-Safe, VAERS
 - Reactogenic: Pain, swelling, HA, Fatigue, Arthralgia, Redness= common AE
 - GBS reporting rate elevated [4.4, 1.8/million doses P and GSK vaccine]
 - FDA/CMS Collaboration: Self-controlled case series CMS data
 - >3.2 million adults 65+: < 10 cases GBS/1 M doses either subunit vaccine

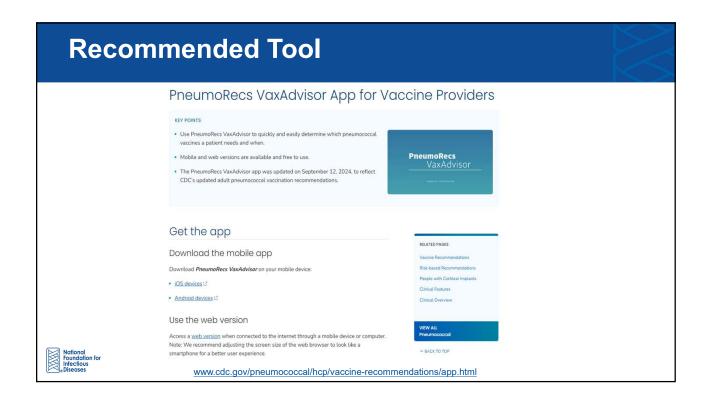


www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01738-0/fulltext www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00796-5/fulltext www.cdc.gov/mmwr/volumes/73/wr/mm7321a3.htm www.medrxiv.org/content/10.1101/2024.12.27.24319702v1









Zoster (Shingles)

- Incidence increases with age to nearly 50% by mid-80s
- Immune compromised are also at increased risk
- Most common complication is post-herpetic neuralgia
- Recent data suggests vaccine reduces risk for dementia
 - Recent press on study showing this with live zoster vaccine no longer used in US







www.cdc.gov/shingles/vaccines/index.html www.nytimes.com/2025/04/02/health/shingles-vaccine-dementia.html www.nature.com/articles/s41591-024-03201-5

Shingles Vaccination

Who: All adults 50+ years

Adults 19+ years with immune compromise

How: 2 doses, 2-6 month interval IM [1 month if time critical]

Safety: Fever, pain in arm, myalgias

SMALL risk for GBS [3-6 excess cases/Million doses vaccine]

The live-attenuated shingles vaccine is no longer available in the US



www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-warning-about-guillain-barre-syndrome-gbs-be-included-prescribing-information-shingrix; www.cdc.gov/shingles/vaccines/index.html

Hepatitis B: Lifespan Vaccination

- Hepatitis B vaccination is the best way to prevent hepatitis B, which is a common worldwide cause for chronic liver disease, cirrhosis, and liver cancer
- Half of US acute hepatitis B cases are in persons 30-49 years, and cases continue to increase in persons age 40-59 years









www.immunize.org/wp-content/uploads/catg.d/p2191.pdf; www.cdc.gov/vaccines/hcp/current-vis/downloads/hep-b.pdf; www.cdc.gov/hepatitis-b/vaccination/index.html

Hepatitis B: Adults < 60 Years

ACIP Approved UNIVERSAL HEPATITIS B Vaccination for Adults <60 years and for those at increased risk >60 years in November 2021

In addition to universal HBV immunization of all infants and persons <19 years

Why universal recommendation is important:

- Low uptake with risk-based recommendation Stigma, Time, Opportunity, Billing
- Opportunity to impact disease: asymptomatic, significant risk of chronic infection, vaccine-preventable cancer



www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm

Hepatitis B: Adults >60 Years

Risk-Based Recommendation:

- Behavioral and social
- Occupational
- Medical
- International Travel: Destination with endemic HBV (community prevalence ≥ 2%)
- Adults 60+ without risk factors MAY be vaccinated to prevent hepatitis B



www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm

HPV Vaccine Impacts: US

- Gargano, et.al. [MMWR] "Cervical precancer incidence decreased 79% and higher-grade precancer incidence decreased 80% among screened women age 20-24 years"
- Dorali, et.al. [JAMA]: "Found a steep decline in cervical cancer mortality among US women younger than 25 years"
- DeKloe, et.al. [JCO] "Males vaccinated for HPV were at decreased odds for HPV-related cancers"





www.cdc.gov/mmwr/volumes/74/wr/mm7406a4.htm https://jamanetwork.com/journals/jama/fullarticle/2827212 https://ascopubs.org/doi/abs/10.1200/JCO.2024.42.16_suppl.10507

HPV Vaccine Impacts: Beyond US

- Scotland: "No cases of invasive cancer were recorded in women immunized at 12 or 13 years irrespective of the number of doses."
- Germany: "The incidence of cervical cancer, which had been rising, has been falling since 2010, with a marked decline among women in all age groups eligible for vaccination"
- Norway: "The findings suggest a significant reduction in the incidence of high-grade cervical precursors following the introduction of the HPV vaccine in Norway's national immunization program"





https://academic.oup.com/jnci/article/116/6/857/7577291 https://pmc.ncbi.nlm.nih.gov/articles/PMC11465478/ www.mdpi.com/2076-393X/12/4/421

HPV Vaccine

- Critically important CANCER PREVENTION
 - Genital cancers and precancers
 - Oropharyngeal cancers
 - HPV-associated genital verruca (warts)
- Ongoing implementation challenges
- Recommended for:
 - ALL 9-26 years

Start series before 15, No IC: 2 doses at 6 months+ interval

Start series at 15+ and/or IC: 3 doses at time 0, 1-2 months, 6+ months

SDM for 27-45 years



Evidence Gaps

Influenza: Impact of home/self-administered LAIV

COVID-19: Impact of 'next generation' vaccines, variants
 RSV: Vaccine benefit in additional patient groups

Pneumococcal: Relative benefit of PCV21 v. 20(15) in adult subgroups

Zoster: Durability of protection [younger IC subgroups, 50+], 'Boost-

ability' of vaccine

HBV: Subgroups: newer vaccines have greatest relative benefit

HPV: Durability of protection by age administered. Benefits with a

single dose



Future Opportunities

- New and updated/improved vaccines
- New vaccine delivery systems
- Improving vaccine confidence
- Increase vaccine uptake
- More robust vaccine tracking/forecasting for adults
- Vaccines for Adults program...



Planning for 2025-2026 Respiratory Season

Scientific Evidence:

- IMMUNIZATION of individuals for whom flu, COVID-19, RSV, and pneumococcal vaccine(s) are indicated and in accord with current CDC recommendations reduces the risk for severe disease [with lesser, albeit important, impact on infection]
- Respiratory vaccines have low risk for moderate/severe adverse events

There are many important uncertainties today...

HHS and subordinate agencies

I will:

- Acknowledge uncertainties, but they WILL NOT define me
- Continue to learn, educate, and advocate for science and prevention in accord with evidence
- Plan for vaccination campaigns to help protect patients



What We Know

- FDA/WHO independently selected influenza strains for 2025-2026 in April
- VRBPAC scheduled 5/22/25 re: COVID-19 strains for 2025-2026
- Manufacturers are planning and making influenza vaccines
- Moderna FDA application for licensure of 2nd-generation vaccine for 2025-2026
- Moderna and Pfizer will be making [current type] vaccines for 2024-2025
- Novavax vaccine remains under consideration for licensure by FDA

There are also many things we do not know ...



Suggestions for Uncertain Times ...

- 1. Follow the science
- 2. Engage in respectful dialogue with those who will do the same with you
- Continue to learn and grow
- 4. Advocate for what you believe in
- 5. Seek out new resources and new opportunities
- 6. DO NOT tune out
- 7. DO NOT waste time and energy on anger or dismay
- 8. REMEMBER: Vaccines have saved millions of lives

We are members of a community—a society in and for which WE CAN MAKE A DIFFERENCE!!



