## AMDAC, VRBPAC, and ACIP Meetings

July 12, 2023

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## Acronyms/Terminology

AMDAC – Antimicrobial Drugs Advisory Committee

VRBPAC – Vaccines and Related Biologic Products Advisory Committee

ACIP – Advisory Committee on Immunization Practices

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## Pre-test

1. T or F  Nirsevimab will the 3rd infant RSV vaccine on the market.
2. T or F  In June, the ACIP reviewed adult RSV vaccine products from 2 manufacturers.
3. T or F  Paralytic polio cases have occurred in 4 states since 2022.
4. T or F  Even with treatment, 10-15% of meningococcal disease cases are fatal.
5. T or F  In North Dakota, the majority of people have gotten a bivalent COVID-19 vaccine.

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## AMDAC June 2023 Topic

- Biologics license application (BLA) 761328, nirsevimab, for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in
  - Neonates and infants born during or entering their first RSV season
  - Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

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## AMDAC – Nirsevimab

- Nirsevimab
  - A monoclonal antibody directed against the prefusion form of the RSV fusion (F) protein to block RSV cell entry
  - In joint development from Sanofi and AstraZeneca
  - It is NOT a vaccine
  - Provides passive immunization
  - Extended serum half-life allows for one dose for the whole RSV season
  - May be added to Vaccines for Children Program
  - Implementation considerations: birth hospitals (bundle), EMR documentation, NDIIS, Billing, Administration

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## AMDAC – Nirsevimab

- Proposed dosing
  - First RSV season: a single 50mg intramuscular (IM) injection for infants weighing <5kg, or a single 100mg IM injection for infants weighing ≥5kg
  - Second RSV season: a single 200mg injection in children less than 24 months of age who remain at increased risk for severe RSV

| | | |
|---|---|---|
| Protect infants born... | Before the RSV season (April – October) | During the RSV season (November – March) |
| When? | At beginning of season | At birth before discharge |
| Where? | In office, during existing well visit before start of season | In hospital |
| How? | Intramuscular injection with pre-filled syringe (stored at 2-8°C) | |

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## AMDAC – Nirsevimab

- Summary
  - Nirsevimab was shown to be 74.5% effective in preventing medically attended RSV lower respiratory tract disease through 150 days
  - Nirsevimab was shown to be effective in preventing RSV hospitalization in infants born at ≥29 to <35 weeks gestational age and there was a trend toward efficacy in infants born at ≥35 weeks gestational age
  - Through extrapolation, nirsevemab was determined to be effective in infants <24 months of age vulnerable to severe RSV disease in their second RSV season
  - No major safety concerns were identified
  - FDA will conduct post-marketing surveillance for safety

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## AMDAC – Nirsevimab

Questions for committee consideration:

1. VOTE: Is the overall benefit-risk assessment favorable for the use of nirsevimab for the prevention of RSV lower respiratory disease in neonates and infants born during or entering their first RSV season?
   Yes 21, No 0
2. VOTE: Is the overall benefit-risk assessment favorable for the use of nirsevimab for the prevention of RSV lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season?
   Yes 19, No 2

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## ACIP June 2023

- RSV Vaccines, Adult*
- Polio Vaccine*
- Influenza Vaccines*
- Pneumococcal Vaccines*
- Dengue Vaccines
- Chikungunya Vaccine
- RSV Vaccines, Pediatric/Maternal
- Mpox Vaccine
- Meningococcal Vaccines
- Vaccine Safety Informational Session
- COVID-19 Vaccines

*Votes scheduled

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## ACIP – Adult RSV Vaccines

- 2 products have received FDA approval
  1. GSK's Arexvy® (adjuvanted RSVpreF3) was approved May 3, 2023 for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years and older
  2. Pfizer's Abrysvo® (bivalent RSVpreF) was approved May 31, 2023 for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years and older
- Final pricing unknown for either product, likely between $200-300
- Would be covered under Medicare Part D

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## ACIP – Adult RSV Vaccines, Arexvy®

- Efficacy and safety evaluated over 2 full RSV seasons
  - 1 dose provided efficacy against RSV-associated lower respiratory tract disease over 2 seasons, including against severe RSV, in people with comorbidities, and across ages
  - A 2nd dose after 12 months did not appear to provide additional efficacy
  - Co-administration with influenza vaccines did not impact immunogenicity or safety
- Study serious adverse events: 3
  - 2 acute disseminated encephalomyelitis
  - 1 Guillain-Barre' syndrome
  - Small number of cases and unknown if linked to vaccine
  - FDA requiring post-licensure studies
  - Providers should weigh risk of adverse events with vaccine benefits and risk of disease

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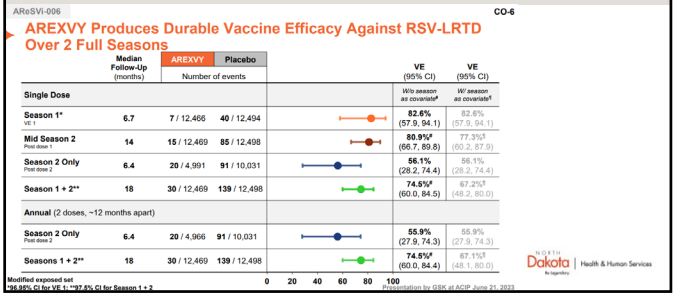
## ACIP – Adult RSV Vaccines, Arexvy®

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## ACIP – Adult RSV Vaccines, Abrysvo®

- Efficacy and safety evaluated over 1.5 RSV seasons
  - 1 dose provided efficacy against RSV-associated lower respiratory tract disease over 1.5 seasons
  - 2nd dose after 12 months appeared to provide minimal additional efficacy
  - Coadministration with influenza vaccines did not impact immunogenicity or safety
- Study serious adverse events
  - 2 Guillain-Barre' syndrome
  - 1 motor-sensory axonal polyneuropathy
- Small number of cases and unknown if linked to vaccine
- FDA requiring post-licensure studies
- Providers should weigh risk of adverse events with vaccine benefits and risk of disease

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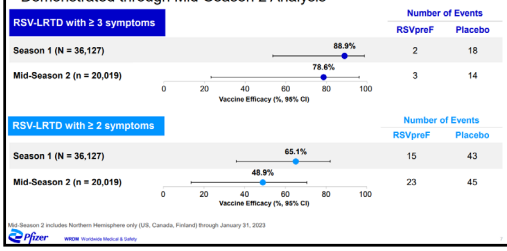
## ACIP – Adult RSV Vaccines, Abrysvo®

Efficacy against RSV-LRTD
– Demonstrated through Mid-Season 2 Analysis




Mid-Season 2 includes Northern Hemisphere only (US, Canada, Finland) through January 31, 2023

Pfizer | WRDW Wordwide Medical & Safety

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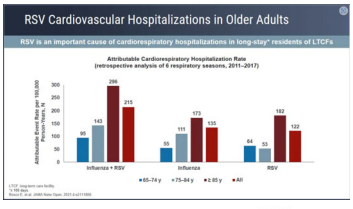
## ACIP – Adult RSV Vaccines

- Each year in the U.S. leads to 177,000 hospitalizations and 14,000 deaths among adults 65 years and older.

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## ACIP – Adult RSV Vaccines

**Age of adults hospitalized with RSV, by race and ethnicity, RSV-NET**

| | N | Median age, years (interquartile range) |
|---|---|---|
| **All** | 9,163 | 70 (58–81) |
| **Race and ethnicity** | | |
| White, non-Hispanic | 5,596 | 73 (62–83) |
| Black, non-Hispanic | 1,731 | 60 (50–70) |
| Hispanic | 713 | 65 (50–77) |
| Asian or Pacific Islander, non-Hispanic | 518 | 77 (64–85) |
| American Indian or Alaska Native, non-Hispanic | 56 | 57 (47–71) |

CDC RSV-NET data 2015–2020 (unpublished) https://www.cdc.gov/rsv/research/rsv-net/index.html

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## ACIP – Adult RSV Vaccines

- Vote #1: Adults 65 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
  Yes 9, No 5
  - 4 of the 5 "No" votes were because members wanted a universal recommendation for this age group
- Vote #2: Adults 60-64 years of age may receive a single dose of RSV vaccine, using shared clinical decision-making.
  Yes 13, No 0, Abstain 1

**Clinical consideration: Shared clinical decision-making based on risk assessment among adults aged 60–64 years**

For shared clinical decision-making recommendations there is no default.

**The decision about whether or not to vaccinate an individual may be informed by:**

- Best available evidence of who may benefit
- An individual's characteristics, values, and preferences
- Health care provider's clinical discretion
- Characteristics of the vaccine being considered

Source: CDC. ACIP Shared Clinical Decision-Making Recommendations. Website: https://www.cdc.gov/vaccines/acip/recs/grade/shared-clinical-decision-making-recommendations.html Last updated February 13, 2023. Accessed June 15, 2023.

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## ACIP – Adult RSV Vaccines

**Adults who may be at higher risk of RSV disease include persons with:**


https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-22/07-RSV-Adults-Britton-508.pdf

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## ACIP – Polio Vaccine

- 1994 Americas certified polio-free
- Adults born and raised in the U.S. can assume they were vaccinated unless they have reason to believe they were not
- July 2022: paralytic polio case in New York
  - Unvaccinated young adult
  - Rockland County history of low vaccine coverage
  - Indicated that there were probably at least 1,000 asymptomatic infections
  - No detection in wastewater samples for last several months
  - Unvaccinated and incompletely vaccinated adults remain susceptible as long as there is ongoing transmission of poliovirus globally

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## ACIP – Polio Vaccine

- Vote #1: Adults (age 18 or older) who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary series with IPV.
  Yes 14, No 0
- Vote #2: Adults who received a primary series of trivalent OPV(tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.
  Yes 14, No 0

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## ACIP – Influenza Vaccines

- Approximately 1-3% of children have an egg allergy by age 3 years, though 2/3 resolve by age 16
- Of the 9 influenza vaccines available during the 2022-23 season, only 2 (Flucelvax and Flublok) were egg-free
- Recommendation has been to receive any available influenza vaccine
  - For history of reactions other than urticaria and an egg-based product being used, administration should be supervised by a healthcare provider to monitor for and manage severe allergic reactions (an additional precaution)
- Both the American Academy of Pediatrics and the American Academy of Allergy, Asthma, & Immunology have stated that no additional precautions are necessary in patients with egg allergies

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## ACIP – Influenza Vaccines

- Vote #1: All persons aged 6 months and older with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipients age and health status can be used.
  Yes 14, No 0
- Vote #2: Affirm the updated MMWR Recommendations and Reports, "Prevention and Control of Seasonal Influenza with Vaccines; Recommendations of the Advisory Committee on Immunization Practices – United States, 2023-24 Influenza Season"
  Yes 14, No 0
- Vote #3: Approve the Vaccines for Children (VFC) resolution for influenza vaccines.
  Yes 14, No 0

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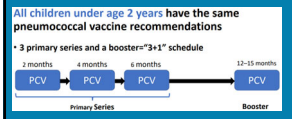
## ACIP – Pneumococcal Vaccines

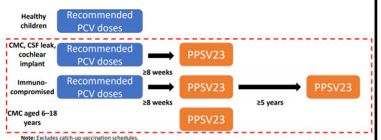
**All children under age 2 years have the same pneumococcal vaccine recommendations**

- 3 primary series and a booster="3+1" schedule




Either PCV13 or PCV15 can be used

**Children with certain underlying conditions are recommended to receive PPSV23 in addition to the recommended PCV doses**




Note: Excludes catch-up vaccination schedules.
CMC=chronic medical conditions, including chronic heart disease, chronic lung disease, diabetes mellitus
CSF=cerebrospinal fluid

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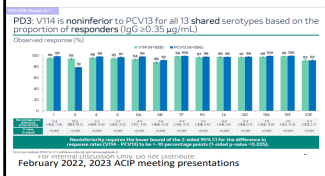
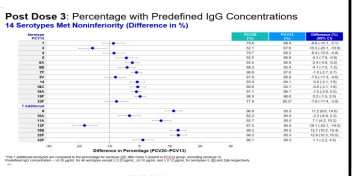
## Both PCV15 and PCV20 were approved based on safety and immunogenicity data compared with PCV13

- **No direct PCV15 vs PCV20 comparison**
- **Unknown clinical implications:**
  - Numerically lower antibody responses vs PCV13
  - Numerically higher antibody response against serotype 3 in PCV15 vs PCV13




February 2022, 2023 ACIP meeting presentations

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## ACIP – Pneumococcal Vaccines

Summary of voting language: No change in PCV doses or schedule

1. Use of either PCV15 or PCV20 is recommended for all children aged 2-23 months according to currently recommended PCV dosing and schedules.
2. Catch-up PCV doses for children aged 24-71 months with an incomplete PCV vaccination status: Use of either PCV15 or PCV20 according to currently recommended PCV dosing and schedules is recommended for
   - Healthy children aged 24-59 months
   - Children with specified risk conditions aged 24-71 months
3. Children aged 2-18 years with any risk condition who have completed their recommended PCV doses before age 6 years
   - Using ≥1 dose of PCV20: No additional doses of any pneumococcal vaccine are indicated
   - Using PCV13 or PCV15 (no PCV20): A dose of PCV20 or PPSV23 using previously recommended doses and schedules is recommended
4. Children aged 6-18 years with any risk condition who have not received any dose of PCV
   - For children aged 6-18 years with any risk condition who have not received any dose of PCV13, PCV15, or PCV20, a single dose of PCV15 or PCV20 is recommended
   - When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks later if not previously given.

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## ACIP – Pneumococcal Vaccines

- PCV13 use for children aged <6 years
  - If only PCV13 is available, it may be given as previously recommended
  - If the series was started with PCV13, it may be completed with PCV15 or PCV20 without additional dose or need to restart
- For children 6-18 years with a risk condition who have previously received only PCV13, either a dose of PCV20 at least 8 weeks later or PPSV23 based on previous dosing and schedules is recommended
- Children who have received hematopoietic stem cell transplant (HSCT) are subject to an alternative schedule

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## ACIP – Pneumococcal Vaccines

- Vote #1: Should PCV20 be recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules, for children aged <2 years in the United States
  Yes 14, No 0
- Vote #2: Should PCV20 without PPSV23 be recommended as an option for pneumococcal vaccination according to currently recommended dosing and schedules, for U.S. children 2-18 years with underlying medical conditions that increase the risk of pneumococcal disease (CMC/IC)
  Yes 14, No 0

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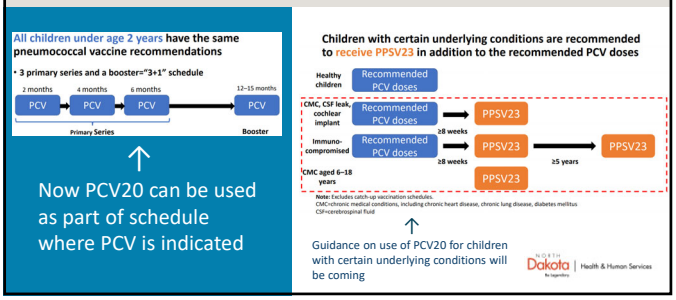
## ACIP – Pneumococcal Vaccines

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## ACIP – Dengue Vaccines

- Dengue is endemic in 6 U.S. territories and freely associated states
- About 1 in 20 people progress to severe dengue
- Highest case numbers and hospitalization rates in ages 10-19 years
- Highest mortality rates in ages ≥20 years
- Dengvaxia® recommended by ACIP in June 2021 for the prevention of dengue disease in people 9-16 years old with:
  - Laboratory confirmation of previous dengue virus infection AND
  - Living in endemic areas
- New vaccine from Takeda (TAK-003) for people ages 4-70 years being reviewed, including policy questions and cost effectiveness
- Several possible recommendations under consideration
- ACIP vote likely in October 2023

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## ACIP – Dengue Vaccines

UPDATE!!!

Yesterday, July 11th, Takeda withdrew the U.S. Biologics License Application (BLA) following discussions with the FDA on aspects of data collection which cannot be addressed during the current BLA review cycle

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## ACIP – Chikungunya Vaccine

Chikungunya – virus spread via mosquito bite

- Symptoms can be prolonged, though death rare
- Outbreaks occur in many places around the world
- No vaccine currently available
- Vaccine from Valneva may be licensed by FDA in August 2023
- ACIP vote likely at February 2024 meeting
- Recommendations for travelers, laboratory workers, and residents of U.S. territories and states with transmission risk

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## ACIP – Pediatric/Maternal RSV Vaccines

Pediatric: nirsevimab

- As previously discussed, AMDAC gave approval to nirsevimab on June 8, 2023
- Classified as a drug, not a vaccine
- 74.5% efficacy against medically attended RSV lower respiratory tract disease through 150 days
- Good safety profile
- Vaccines for Children?
- Cost?
- Timing?

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## ACIP – Pediatric/Maternal RSV Vaccines

Maternal: bivalent RSV Prefusion (RSVpreF) vaccine

- One dose at 24-36 weeks gestation to provide passive immunity to infants against LRTI and severe LRTI caused by RSV
- 81.8% effective against RSV lower respiratory tract protection within 90 days of birth and 69.4% within 180 days of birth
- Higher incidence of preterm birth in vaccine group (5.6%) than placebo group (4.7%), though not statistically significant – trial underpowered to detect a 20% relative increase in preterm birth
- Good safety profile in pregnant recipients

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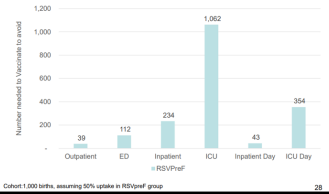
## ACIP – Pediatric/Maternal RSV Vaccines

Maternal: bivalent RSV Prefusion (RSVpreF) vaccine

**Results: Number Needed to Vaccinate**




Cohort:1,000 births, assuming 50% uptake in RSVpreF group

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## ACIP – Pediatric/Maternal RSV Vaccines

Maternal: bivalent RSV Prefusion (RSVpreF) vaccine

- Co-administration with Tdap, flu, COVID-19
  - In Pfizer's Phase 2b study in non-pregnant women, co-admin of Tdap and RSVpreF led to decreased response to pertussis components – limited data
- Timing?
- Cost? Less than nirsevimab?
- Efficacy on subsequent pregnancies?
- Safety of additional doses in subsequent pregnancies
- Additional pregnancy vaccine, uptake?
- Post-approval safety monitoring

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## ACIP – Pediatric/Maternal RSV Vaccines

**Seasonal rate of RSV-associated hospitalizations per 1,000 children among American Indian and Alaska Native children <5 years of age, Nov 2019- May 2020 (SuNA)***

| Age | Chinle, Arizona | Whiteriver, Arizona | Anchorage, Alaska | Yukon-Kuskokwim Delta, Alaska | NVSN** for comparison |
|---|---|---|---|---|---|
| 0-5 Months | 83.0 (52.0, 132.5) | 70.4 (36.3, 136.6) | 35.7 (20.4, 62.6) | 132.3 (98.2, 178.1) | 21.6 (20.0, 23.3) |
| 6-11 Months | 61.6 (35.9, 105.8) | 90.1 (50.0, 162.3) | 0.0 (0.0, 10.8) | 91.6 (64.0, 131.0) | 8.2 (7.1, 9.3) |
| **0-11 Months** | **71.8 (50.4, 102.4)** | **80.6 (51.9, 125.2)** | **19.2 (11.2, 33.0)** | **112.2 (89.3, 141.0)** | **14.9 (13.9, 16.0)** |
| **12-23 Months** | **42.1 (27.2, 65.3)** | **38.7 (22.0, 68.1)** | **15.6 (8.7, 27.7)** | **26.4 (16.6, 41.8)** | **4.5 (3.9, 5.2)** |
| 24-59 Months | 10.9 (6.8, 17.4) | 8.2 (4.2, 16.0) | 1.1 (0.3, 3.8) | 5.9 (3.2, 10.9) | 1.2 (1.2, 1.5) |
| 0-59 Months | 27.2 (21.4, 34.4) | 25.4 (18.7, 34.5) | 7.7 (5.3, 11.1) | 32.7 (26.9, 39.7) | 4.6 (4.3, 4.8) |

*Hartman et al, RSV2022 12th International Symposium, Belfast 9/29/2022-10/2/2022; Atwell et al. RSV among American Indian and Alaska Native children: 2019-20 (manuscript in press) SuNA = RSV Surveillance among Native American Persons
**Incidence of RSV-associated hospitalization in 2019-2020 included for comparison. NVSN = New Vaccine Surveillance Network.

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## ACIP – Pediatric/Maternal RSV Vaccines

- What if both products are approved?
  - Some pregnant women do not have access to or get prenatal care
  - Maternal vaccination status may be unknown
  - Birth dose processes
  - One or the other?
  - Both?

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## ACIP – Mpox Vaccine

- In February 2023, ACIP vote: recommend 2-dose Jynneos series (28 day separation) in people 18 and older at risk of mpox during an outbreak as defined by public health authorities
- Updates on epidemiology, safety, and effectiveness
  - Good safety profile
- Chicago case cluster: March 18-June 12, 40 laboratory confirmed cases
  - 55% vaccinated with 2 doses JYNNEOS (median time from 2nd dose to diagnosis was 8.4 months) or 1 dose ACAM2000
  - 13% were partially vaccinated
  - 33% were unvaccinated

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## ACIP – Mpox Vaccine

### Pre-exposure prophylaxis: Use of JYNNEOS during mpox outbreaks

- For research laboratory personnel* and clinical laboratory personnel performing diagnostic testing for mpox[§], ACIP recommends use of JYNNEOS for pre-exposure vaccination as an alternative to ACAM2000
- For clinical laboratory personnel who handle specimens that may have a higher possibility of containing replication competent MPXV (e.g., lesion material, throat swabs, oral swabs, rectal swabs), and certain healthcare personnel who care for patients infected with mpox or administer ACAM2000[§], ACIP recommends use of JYNNEOS (as an alternative to ACAM2000) based on shared clinical decision-making

*Research laboratory personnel are those who directly handle cultures or animals contaminated or infected with monkeypox virus (MPXV)
[§]Vaccination is not routinely recommended for clinical laboratory personnel who perform routine chemistry, hematology, and urinalysis testing, including for patients with suspected or confirmed MPXV infection, healthcare personnel who care for patients with mpox or administer ACAM2000. Recommended infection prevention and control practices are effective in minimizing transmission. Vaccination can be offered based on site- and activity- specific biosafety risk assessments (e.g., identification of laboratory procedures with a high likelihood of generating aerosols or inadequate PPE availability)

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## ACIP – Mpox Vaccine

- Coadministration of JYNNEOS with COVID-19 vaccines
  - May consider waiting 4 weeks between vaccines, particularly adolescent and young males
  - Observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus and COVID-19 vaccines and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine
  - If increased risk for mpox or severe disease due to COVID-19, neither vaccine should be delayed

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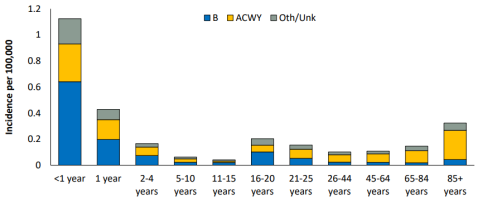
## ACIP – Meningococcal Vaccines

Average Annual Meningococcal Disease Incidence by Age Group and Serogroup — United States, 2010–2022*




Source: NNDSS data with additional serogroup data from the Active Bacterial Core Surveillance System and state health departments
*2022 data are preliminary

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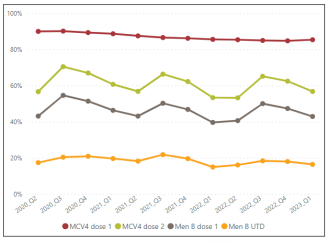
## ACIP – Meningococcal Vaccines

MCV4: percent of North Dakota teens 16-17 years of age by the last day of the quarter who have received the specified number of doses

MenB: percent of ages 13-17 years of age who received at least 1 dose and percent of ages 16-17 who are series up to date

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## ACIP – Meningococcal Vaccines

| Current vaccination | |
|---|---|
| **First dose** | **Second dose** |
| At 11-12 yrs old with MenACWY | At 16 yrs old with MenACWY |
| At 16 yrs old with Men B | At 16 yrs old with Men B |

| Potential vaccination strategies | | | |
|---|---|---|---|
| **First dose** | **Second dose** | **Third dose** | **Key Label** |
| At 11-12 yrs old with MenACWY | At 16 yrs old with MenABCWY | At 16 yrs old with MenB | Q-P-B |
| At 11-12 yrs old with MenABCWY | At 16 yrs old with MenABCWY | None (N) | P-P-N |
| At 11-12 yrs old with MenACWY | At 16 yrs old with MenABCWY | At 16 yrs old with MenABCWY | Q-P-P |
| At 11-12 yrs old with MenABCWY | At 16 yrs old with MenABCWY | At 16 yrs old with MenABCWY | P-P-P |

Men ABCWY = Potential pentavalent vaccine (P) with serogroups A, B, C W Y
Men ACWY = currently recommended quadrivalent vaccine (Q) for serogroups A, C, W, Y,
Men B =currently recommended monovalent vaccine for serogroup B

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## ACIP – Meningococcal Vaccines

Initial vaccine effectiveness by vaccine and serogroup

| | QUADRIVALENT | | | MEN B | | | PENTAVALENT | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Base-case** | **Low** | **High** | **Base-case** | **Low** | **High** | **Base-case** | **Low** | **High** |
| First DOSE Men ACWY | **93%** | 73% | 98% | | | | **94%** | 62% | 96% |
| 2nd + DOSE Men ACWY | **97%** | 73% | 98% | | | | **97%** | 94% | 99% |
| First DOSE Men B | | | | **60%** | -- | -- | **60%** | | |
| 2nd + DOSE Men B | | | | **85%** | 50% | 99% | **88%** | 79% | 99% |

Values and assumptions on initial protection are based on various sources:
Phase 3 noninferiority initial vaccine efficacy by single dose (at 11-12yrs) and second-dose (16yrs) of pentavalent (Men ABCWY) vaccine as reported by Pfizer (data on file).
Cohn AC, MacNeil JR, Harrison LH, et al. Active Bacterial Core Surveillance (ABCs) Team and MeningNet Surveillance Partners. Effectiveness and Duration of Protection of One Dose of a Meningococcal Conjugate Vaccine. Pediatrics. 2017 Feb;139(2):e20162193. doi: 10.1542/peds.2016-2193. PMID: 28100689; PMCID: PMC5353279.

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## ACIP – Meningococcal Vaccines

- Overall low incidence of disease, but…
  - Even with treatment, about 10-15% of cases are fatal
  - Even with treatment, about 10-20% of survivors have permanent sequelae
- Pentavalent meningococcal vaccine MenABCWY from Pfizer in Phase 3 trial
- Draft proposal from Work Group to the ACIP: For individuals aged 10 years or older, Pfizer's MenABCWY vaccine may be used as an alternative to MenACWY and MenB vaccines only when both vaccines are indicated to be given at the same time. This proposal applies to health individuals (routine schedule) and those at increased risk for meningococcal disease.

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## ACIP – Vaccine Safety Informational Session

- Conclusions from CDC and other experts review of vaccine safety data:
  - No association between the number of vaccine-delivered antigens young children receive and likelihood of ED or inpatient encounters for infections
  - No evidence that current recommended schedule "overwhelms" the immune system
  - No association between the current recommend schedule with an increased risk of Type 1 Diabetes
  - Decreased risk of T1DM at higher vaccine aluminum exposure: modest effect size; more study needed
  - Small positive association between cumulative vaccine-associated aluminum before 24 months and persistent asthma from 24-59 months
    - Several study strengths and numerous limitations
    - Further investigations ongoing
  - The totality of the available evidence, including results from the studies which were presented at the ACIP meeting, continues to support the safety of the current childhood immunization schedule in the U.S. - benefits of vaccination strongly outweigh known and potential risks

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## ACIP – COVID-19 Vaccines

- Trends in COVID-19-associated hospitalizations – COVID-NET, March 2020 – May 2023:
  - Hospitalization rates decreased in all age groups
  - Most pregnant and hospitalized with a positive COVID test were not up to date with vaccinations
  - Infants <6 months had similar hospitalization rates to adults ages 65-75 years
- Hybrid immunity appears to result in stronger, more robust immune response
- Neutralizing antibody titers in people with hybrid immunity may wane slower than in people vaccinated without infection
- T-cell immune response from both infection and vaccination well preserved against Omicron – likely important in preventing severe disease

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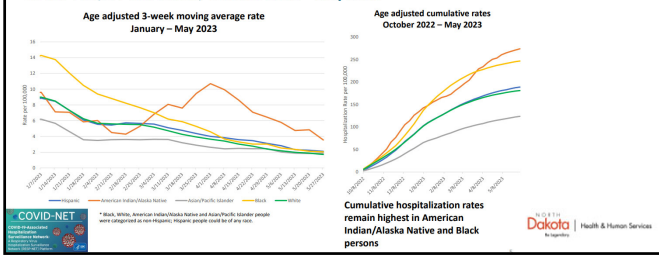
## ACIP – COVID-19 Vaccines

**COVID-19-associated hospitalization rates by race and ethnicity* — COVID-NET, 14 U.S. States, October 2022 – May 2023**




**Cumulative hospitalization rates remain highest in American Indian/Alaska Native and Black persons**

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## ACIP – COVID-19 Vaccines

U.S. COVID-19 Vaccination Coverage (%) of Total Population by Age Group – May 10, 2023

| Coverage / Age (years) | <2 | 2-4 | 5-11 | 12-17 | 18-24 | 24-49 | 50-64 | ≥65 |
|---|---|---|---|---|---|---|---|---|
| At least one dose† | 8.9 | 10.9 | 40.0 | 72.2 | 82.3 | 85.5 | 95.0 | 95.0 |
| At least one bivalent dose | 0.6 | 0.6 | 4.8 | 7.8 | 7.4 | 12.1 | 21.7 | 43.3 |
| Unvaccinated | 91.1 | 89.1 | 60.0 | 27.8 | 17.7 | 14.5 | —† | —† |

ND COVID-19 Vaccination Coverage by Age Group – July 3, 2023


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## ACIP – COVID-19 Vaccines

- COVID-19 vaccines and treatments anticipated to transition to the commercial marketplace Fall 2023
- Most Americans will continue to pay nothing out-of-pocket for COVID-19 vaccine due to insurance coverage
- Uninsured adults set to lose access to affordable access to COVID-19 vaccines and treatments

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## ACIP – COVID-19 Vaccines

- **Bridge Access Program for COVID-19 Vaccines and Treatment**
  - Public-private partnership
  - CDC will provide COVID-19 for uninsured adults through December 2024
  - Providers must be enrolled in the Prevention Partnership (VFC/317) program to receive vaccine
    - Some pharmacies will receive vaccine directly from CDC
  - HRSA is providing funding to a network of FQHCs to administer vaccine
  - NDHHS currently writing a grant to support this program. *May* be able to provide funding to providers to cover administration fees.
  - More information to come
  - Privately purchased vaccine should be used for insured adults and their insurance billed

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## ACIP – COVID-19 Vaccines

**Current recommendations for mRNA COVID-19 vaccines**

| 6 months – 4 years | 5 years | ≥6 years |
|---|---|---|
| 2 doses bivalent Moderna OR 3 doses bivalent Pfizer-BioNTech | 2 doses bivalent Moderna OR 1 dose bivalent Pfizer-BioNTech | 1 dose bivalent Moderna OR 1 dose bivalent Pfizer-BioNTech |

***Possible* future recommendations for simplification**

mRNA COVID-19 vaccines

| 6–23 months | ≥2 years |
|---|---|
| 2 doses bivalent Moderna OR 3 doses bivalent Pfizer-BioNTech | 1 dose bivalent Moderna OR 1 dose bivalent Pfizer-BioNTech |

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## VRBPAC – COVID-19 Vaccine Composition

- COVID-19 Vaccine Composition
  - Efficacy of initial monovalent and subsequent bivalent products evaluated
  - Review of SARS – CoV-2 variant proportion estimates and estimated number of cases by variant to identify the dominant strains over time
  - Current COVID-19 vaccines appear less effective against current dominant circulating variants than against previous virus strains
  - Omicron XBB lineage emerged in fall 2022
  - All circulating viruses at greater than 1% of cases are XBB lineages with same spike sequence
  - Preclinical data from vaccine manufacturers show that XBB.1 descendent lineage-containing vaccines elicit higher neutralizing antibody response to currently circulating variants than currently approved vaccines

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## VRBPAC – COVID-19 Vaccine Composition

- COVID-19 Vaccine Composition
  - Vote: For the 2023-2024 Formula of COVID-19 vaccines in the U.S., does the committee recommend a periodic update of the current vaccine composition to a monovalent XBB-lineage?
    Yes 21, No 0
- Rollout anticipated fall 2023
- Committee discussion favored XBB.1.5 over XBB.1.16 or XBB.2.3 due to available data and manufacturer production status

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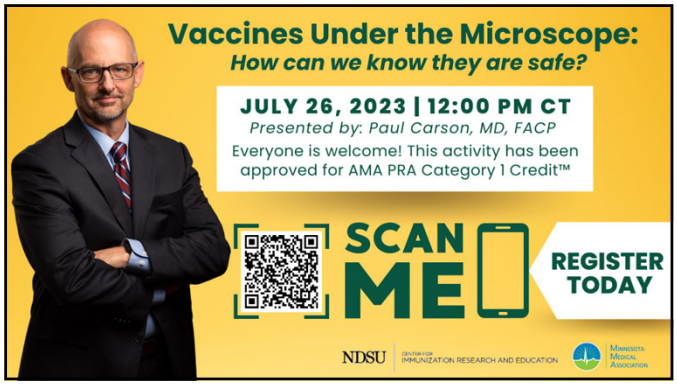


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## Post-Test

- Post-test
  - Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_1NulCAHrovj9sX4
  - Successfully complete the five-question post-test to receive your certificate
  - Credit for this session will not expire until August 8, 2023.
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations

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## AMDAC, VRBPAC, and ACIP Meetings

July 10, 2023

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## AMDAC, VRBPAC, and ACIP Meetings

References:

FDA.gov, June 8, 2023: Meeting of the Antimicrobial Drugs Advisory Committee Meeting Announcement - 06/08/2023 | FDA

FDA.gov, Vaccines and Related Biological Products Advisory Committee June 15, 2023 Meeting Announcement - 06/15/2023 | FDA

CDC.gov, ACIP Live Meeting Archive – June 21-23, 2023 (cdc.gov)

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