

# **Updates from the June 2024 ACIP Meeting**

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The Summit Weekly Update July 11, 2024

# **RSV Vaccines – Adults**

### **Background: RSV Vaccines for Older Adults**

- In June 2023, CDC and ACIP recommended that adults aged 60 years of age and older may receive a single dose of RSV vaccination, using shared clinical decision-making
  - A number of uncertainties contributed to ACIP making a recommendation for shared clinical decision-making

#### FDA licensure in 2024:

- May 2024: Moderna's vaccine for prevention of lower respiratory tract disease caused by RSV infection in adults aged 60 years and older
- June 2024: Expanded age indication for GSK's RSV vaccine, licensed for the prevention of RSV lower respiratory tract disease in adults 50 through 59 years of age who are at increased risk for lower respiratory tract disease caused by RSV

### **Summary: Vaccine Effectiveness**

- Under real-world conditions, RSV vaccination (GSK or Pfizer) provided protection against severe RSV disease among US adults aged ≥60 years in this first season of use
- These results build on those from RSV vaccine trials in two ways:
  - Provide evidence of VE against RSV-associated ED visits, hospitalizations, and critical illness
  - Demonstrate protection in a population that more closely represents those at high-risk of severe RSV disease, including
    - Adults aged 75 years or older
    - Adults with a composite of various immunocompromising conditions
    - Adults with underlying conditions, especially cardiopulmonary disease
- Ongoing monitoring of RSV VE is needed to confirm findings from this season and assess durability of RSV vaccine protection

# CDC and ACIP have heard feedback that the RSV SCDM recommendation has been difficult to implement

- Standing orders often used by medical assistants, nurses, and pharmacists – are difficult under SCDM.
- SCDM conversations are challenging and time consuming.
- Approximately 80% of all older adult RSV vaccinations have been given in pharmacies. Not all providers who give vaccines are comfortable with the SCDM conversation or feel it is within their scope of practice.
- In the specific instance of RSV vaccines, there are also concerns about the ability to complete the type of risk-benefit discussion intended by ACIP with the RSV SCDM recommendation.

### **Policy questions**

- Should all adults aged ≥75 years be recommended to receive a single dose of RSV vaccination?
- Should adults aged 60–74 years at increased risk of severe RSV disease be recommended to receive a single dose of RSV vaccination?
- Should adults aged 50–59 years at increased risk of severe RSV disease be recommended to receive a single dose of RSV vaccination?

# Public health problem: summary of the available evidence Adults 60 years and older

- Annual rate of RSV-associated hospitalization increases with increasing age, with a steep rise at age 75 years.
- Certain chronic medical conditions also increase risk of RSV-associated disease. Age and chronic medical conditions are independently associated with increased risk.
- RSV is associated with severe disease and has significant posthospitalization sequelae among older adults.

## **Work Group Considerations**

- The shared clinical decision-making (SCDM) recommendation was made in the setting of uncertainty about both the estimated benefits and potential risks of RSV vaccination.
- Now there is real-world evidence of robust protection against RSV-associated hospitalization during the first season after vaccination among adults 60 and older, including among adults 75 and older and adults with chronic medical conditions.
- On the other hand, uncertainty remains regarding the magnitude of potential risk of Guillain-Barre syndrome (GBS).
- The Work Group believes the GBS signal continues to warrant close attention and additional follow-up.
- A transition from SCDM to a universal recommendation among adults 75 years and older and a risk-based recommendation among adults aged 60–74 years and is intended to:
  - Maximize vaccination among persons most likely to benefit among whom we now have real-world evidence of protection
  - Minimize vaccination among persons least likely to benefit while additional safety data accrue

#### **ACIP** recommendations

- 1. ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccination.<sup>a,b</sup>
- 2. ACIP recommends adults 60–74 years of age who are at increased risk of severe RSV disease<sup>c</sup> receive a single dose of RSV vaccination.<sup>a,b</sup>
- a. RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.
- b. These recommendations would supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are <u>not</u> at increased risk of severe RSV disease would NOT be recommended to receive RSV vaccination.
- c. The Clinical Considerations presentation will describe chronic medical conditions and other risk factors for severe RSV disease proposed to be named in this risk-based recommendation.

The decision to postpone making a recommendation is primarily driven by uncertainty in the balance of estimated benefits of RSV vaccine and potential risk of GBS, specifically among adults aged 50–59 years

- Among adults aged 50-59 years, in whom the absolute rates of RSV-associated disease are lower, the balance of risk and benefits is more uncertain than among older age groups.
- The Work Group recognizes that postponing a policy recommendation may mean some adults aged 50–59 years who might benefit from RSV vaccination will not receive a dose this fall.
- The Work Group will continue active deliberation on the best policy recommendation in this age group as more data become available and will bring a recommendation for ACIP's consideration as soon as the Work Group believes there is sufficient evidence.

# DTaP-IPV-Hib-HepB (Vaxelis®) Vaccine

### Background

- PRP-OMP (PedvaxHIB) is preferentially recommended for American Indian and Alaska Native (AI/AN) infants
  - It provides a protective antibody response after the first dose
  - Historically, Hib meningitis peaked at an earlier age among AI/AN infants
- Vaxelis (DTaP-IPV-Hib-HepB) does not currently have a preferential recommendation for AI/AN infants because
  - It contains PRP-OMP in a lower amount than PedvaxHIB
  - Post-dose 1 immunogenicity data were not previously available
- A recent clinical trial (presented at the February ACIP meeting) of Vaxelis compared with PedvaxHIB demonstrated a non-inferior immune response post-dose 1 in American Indian and Alaska Native infants

#### **ACIP** recommendation

ACIP recommends DTaP-IPV-Hib-HepB (Vaxelis®) should be included with PRP-OMP (PedvaxHIB®) in the preferential recommendation for American Indian and Alaska Native infants based on the *Haemophilus influenzae* type b (Hib) Hib component.

# **Chikungunya Vaccine**

## Live attenuated chikungunya vaccine

- Manufactured by Valneva as IXCHIQ
- Licensed November 9, 2023
- Age group currently adults ≥18 years
- Single dose schedule



## Background

- The Chikungunya Vaccines Work Group was formed in May 2022
- The Work Group is developing policy options for ACIP's consideration for use of chikungunya vaccine among U.S. persons at risk of chikungunya
  - Travelers
  - Laboratory workers
  - Residents of U.S. territories and states with risk of transmission
- In February 2024 ACIP made recommendations for use of the live attenuated chikungunya vaccine among travelers and laboratory workers at risk of chikungunya
- The Work Group is now discussing use in U.S. territories and states with risk of transmission

# Chikungunya in U.S territories and affiliated states

- Since 2013, 3 territories and 2 affiliated states have had chikungunya outbreaks
- Outbreaks were explosive
- For Puerto Rico and USVI, ~30% of population was likely infected, with 20%–25% of the population having clinical illness mainly during a period ~6 months
- No evidence of confirmed transmission since 2017 (Puerto Rico) or earlier in islands with smaller populations
- Timing of future transmission or outbreaks and likely pattern unknown

# Consideration of recommendations for use of chikungunya vaccine in at-risk U.S. territories

- Work Group gathering data and will discuss additional important considerations including:
  - Acceptability and value of vaccine to providers and relevant populations
  - Feasibility of administration

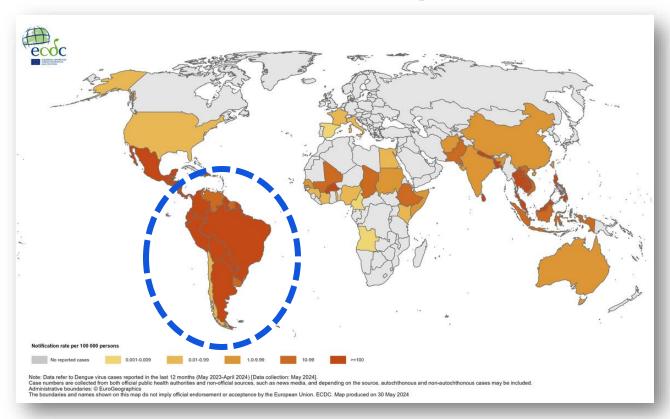
## Virus-like particle chikungunya vaccine

- Manufactured by Bavarian Nordic
- Submission of BLA to FDA completed on June 17, 2024
- Licensure possible first half of 2025
- Intended age group is adolescents and adults aged ≥12 years
- Single dose schedule

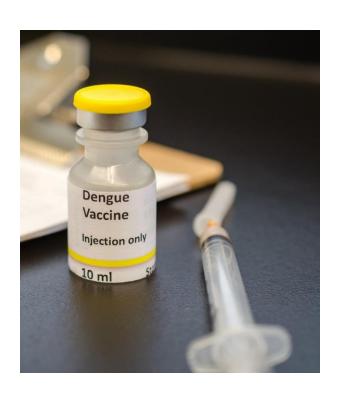
# **Dengue Vaccine**

# Countries reporting locally acquired dengue

cases, March 2023-April 2024



## **Dengvaxia™ ACIP Recommendation June 2021**



Three doses of Dengvaxia are indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3, and 4 in people 9–16 years old with:

laboratory confirmation of previous dengue virus infection

AND

living in endemic areas.

# CDC has updated its website with information on discontinuation of Dengvaxia.

#### Dengue Vaccine

#### Español (Spanish) Print

A dengue vaccine is approved for use in children aged 9–16 years with laboratory-confirmed previous dengue virus infection and living in areas where dengue is endemic (occurs frequently or continuously). Endemic areas include some U.S. territories and freely associated states. The vaccine is not approved for use in U.S. travelers who are visiting but not living in an area where dengue is common.

The dengue vaccine is available in Puerto Rico and is part of the routine childhood <u>immunization schedule</u>. Most health insurance plans cover routine vaccinations. The Vaccines for Children (VFC) program also provides vaccines for children 18 years and younger who are uninsured, underinsured, Medicaid-eligible, American Indian, or Alaska Native.

Sanofi-Pasteur will stop manufacturing its dengue vaccine for children. The manufacturer is discontinuing the vaccine citing a lack of demand in the global market to continue production of this vaccine. CDC, in collaboration with the Puerto Rico Department of Health, will continue alerting health professionals about the discontinuation of Dengvaxia and the use of this vaccine as recommended by the Advisory Committee on Immunization Practices (ACIP). Dengvaxia is safe and effective when administered as recommended. There are two other dengue vaccines either approved or in late stages of development. However, they are not currently available in the United States. People can continue to protect themselves and their families from dengue by <u>preventing mosquito bites</u> and <u>controlling mosquitoes</u> in and around their homes.

# **COVID-19 Vaccines**

### **COVID-19 vaccine 2024-2025 Formula: VRBPAC Meeting**

- June 5, 2024: FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss strain selection for 2024-2025 COVID-19 vaccines
  - Based on the totality of the evidence presented, FDA advised manufacturers to develop monovalent JN.1 lineage COVID-19 vaccines, with a preference for the KP.2 strain, if feasible
  - Anticipated 2024-2025 vaccine doses will be broadly available in the fall

# **Evidence to Recommendations (EtR) Framework**Policy Question

 Should 2024 – 2025 COVID-19 vaccines be recommended for use in persons ≥6 months of age?

- Products and ages under review for authorization or approval by FDA include:
  - Moderna COVID-19 vaccine for ages 6 months and older
  - Novavax COVID-19 vaccine for ages 12 years and older
  - Pfizer-BioNTech COVID-19 vaccine for ages 6 months and older

FDA: Food and Drug Administration

# Work Group Interpretation: Considerations for Universal Recommendation

- Work Group began deliberations considering both universal and non-universal policy options, but non-universal options had significant implementation challenges
  - Risk based recommendations would not allow access to COVID-19 vaccines for those not in a defined risk group
    - The current list of conditions that increase risk of severe illness due to COVID-19<sup>1</sup> is extensive and includes the majority of the US adult population<sup>2</sup>
    - There are no groups without a risk of severe illness
  - Shared clinical decision (SCDM) making would create barriers to vaccination, may not effectively target those at highest risk, and would likely increase inequities in vaccine access
  - COVID-19 epidemiology remains uncertain and universal recommendations would need to be considered if there was an unexpected increase in burden following a risk-based or SCDM decision
- COVID-19 disease burden remains substantial, and consistent recommendations may increase coverage over time

<sup>1.</sup> https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Overweight and obesity are considered conditions with conclusive or suggestive evidence of increasing risk and have a combined prevalence >70%. National Health Statistics Reports; https://stacks.cdc.gov/view/cdc/106273

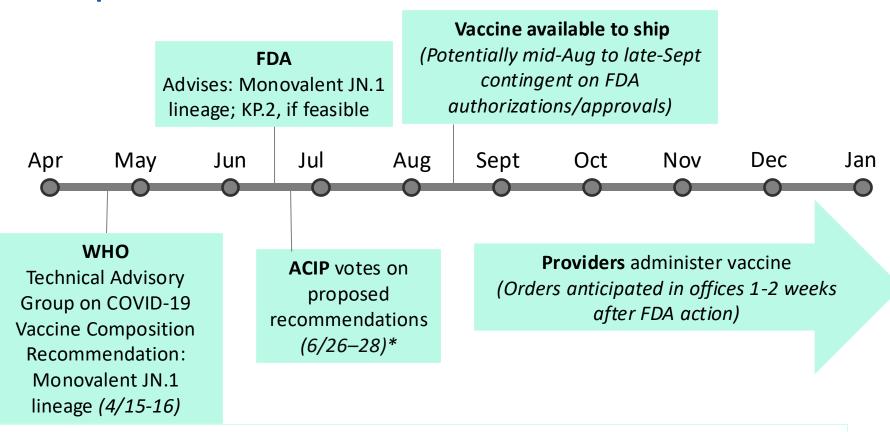
### **Summary of Work Group Interpretation**

- Benefits of COVID-19 vaccination vary by age and risk status
  - Under a universal recommendation, 2024-2025 COVID-19 vaccines will be available to all persons ages ≥6 months
  - Additional implementation efforts should be targeted toward those that will receive the most benefit from COVID-19 vaccination, including people ≥65 years old, people with underlying conditions¹ including immunocompromise, and pregnant people to protect themselves and their infants
- The Work Group will continue to evaluate COVID-19 vaccine policy, including the need for a universal recommendation, particularly as COVID-19 epidemiology continues to change

### **ACIP** recommendation

ACIP recommends 2024-2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥6 months of age

### **Prospective 2024 COVID-19 vaccine timeline**



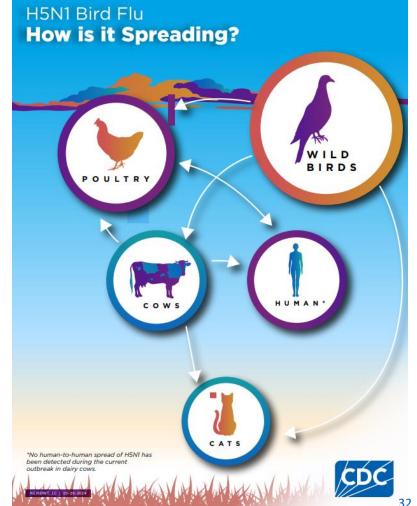
<sup>\*</sup>CDC publishes MMWR policy note following ACIP and FDA action (potentially late August to late September).

<sup>\*\*</sup>CDC updates COVID-19 Vaccine Interim Clinical Considerations immediately following FDA action.

# Influenza Vaccines

### Public Health Risk

- Overall risk to the public remains low
- Increased risk with exposure to infected animals or environment (occupational, recreational)
- Exposed individuals should monitor for symptoms after first exposure and for 10 days after last exposure



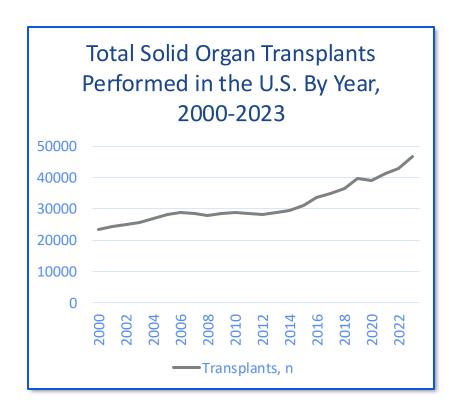
#### U.S. Influenza Vaccine Composition for the 2024-25 Influenza Season

- All influenza vaccines marketed in the United States for the 2024-25 season will be trivalent
- There will be no influenza B/Yamagata component, following no confirmed detections of wild-type influenza B/Yamagata viruses since March 2020
- U.S. influenza vaccine composition for 2024-25 includes an update to the influenza A(H3N2) component:
  - An A/Victoria/4897/2022 (H1N1)pdm09-like virus for egg-based vaccines
     or an A/Wisconsin/67/2022 (H1N1)pdm09-like virus for cell and recombinant vaccines;
  - An A/Thailand/8/2022 (H3N2)-like virus for egg-based vaccines
     or an A/Massachusetts/18/2022 (H3N2)-like virus for cell and recombinant vaccines;
  - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

### **ACIP** recommendation

ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications.

### **Solid Organ Transplantation in the United States**



U.S. Organ Transplants Performed, 2023		
All	46,632 (100)	
By age group	N (%)	
<18 years	1,916	(4)
18-64 years	33,610	(72)
≥65 years	11,104	(24)
Organ(s)	N (%)	
Kidney	27,332	(59)
Liver	10,660	(23)
Heart	4,545	(10)
Lung	3,026	(6)
Kidney/pancreas	812	(2)
Pancreas	102	(0.2)
Heart/lung	54	(0.1)

National Data, Organ Transplant and Procurement Network (OPTN). National data - OPTN (hrsa.gov)

#### Public Health Importance—Disease Burden

- SOT recipients require lifelong immunosuppressive medications.
- Manifestations of influenza can be more severe
  - Lower respiratory tract disease, including pneumonia, occurs in 22-49% of SOT recipients
- In a 5-year cohort of SOT recipients with influenza (n=477):
  - 21% had lower respiratory tract disease on presentation
  - 69% were hospitalized
  - 11% admitted to an intensive care unit
  - 8% required mechanical ventilation
  - 3% died (all-causes) within 30 days

#### **ACIP** recommendation

ACIP recommends high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines as acceptable options for influenza vaccination of solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens, without a preference over other age-appropriate IIV3s or RIV3.

## **Pneumococcal Vaccines**

#### **Adult Pneumococcal Vaccines**

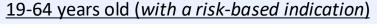
	1	3	4	5			8	9	9	3	2	3	0	1	2	5	9 N	7	0	5	5	6	3	3	4	1	3 5 B
PCV15																											
PCV20																											
PPSV23																											
PCV21																											

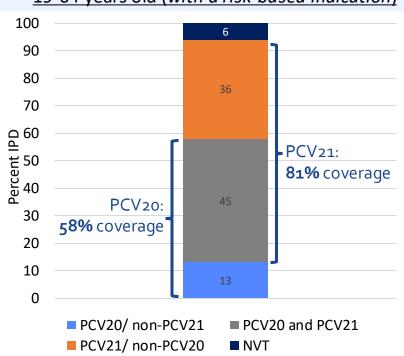
#### 21-valent pneumococcal conjugate vaccine (CAPVAXIVE™, Merck):

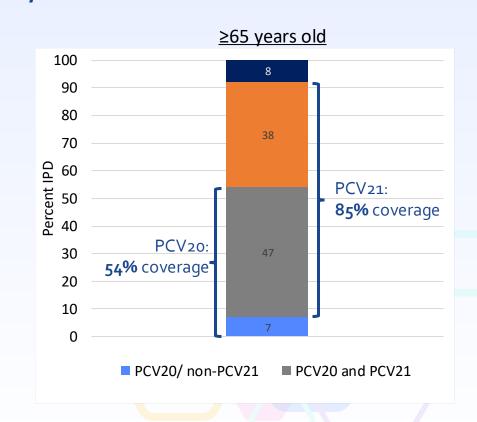
Approved by the FDA for adults aged ≥18 years on June 17, 2024¹

PCV13=13-valent pneumococcal conjugate vaccine PCV15=15-valent pneumococcal conjugate vaccine PCV20=20-valent pneumococcal conjugate vaccine PPSV23=23-valent pneumococcal polysaccharide vaccine

### Proportion of IPD by vaccine-type among adults with a pneumococcal vaccine indication, 2018-2022







#### **Current Pneumococcal Vaccine Recommendations for Adults**

- The following groups are currently recommended to receive a dose of pneumococcal conjugate vaccine (PCV):
  - Adults aged ≥65 years who have not received a PCV¹
  - Adults aged 19–64 years with certain underlying conditions or risk factors<sup>2</sup> who have not received a PCV<sup>1</sup>
  - Certain adults who have received PCV13 but have not received PCV203

- Excludes PCV7
- 2. alcoholism; chronic heart, liver, or lung disease; chronic renal failure; cigarette smoking; cochlear implant; congenital or acquired asplenia; CSF leak; diabetes mellitus; generalized malignancy; HIV infection; Hodgkin disease; immunodeficiency; iatrogenic immunosuppression; leukemia, lymphoma, or multiple myeloma; nephrotic syndrome; solid organ transplant; or sickle cell disease or other hemoglobinopathies
- 3. Adults who have not completed the recommended vaccine series, or shared clinical decision-making for adults aged ≥65 years who have completed the recommended vaccine series Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

### **Policy Questions Being Considered by the Work Group**

- 1. Should PCV21 be recommended for U.S. adults aged ≥19 years who currently have a recommendation to receive a PCV?
  - Adults aged ≥65 years who have never received a PCV
  - Adults aged 19–64 years with a risk condition, who have never received a PCV
  - Adults aged ≥19 year who have received a PCV (i.e., PCV7 or PCV13), but have not completed the recommended series
  - PCV20 use based on shared clinical decision-making for adults ≥65 years who have completed the recommended series with PCV13 and PPSV23
- 2. Should PCV21 be recommended for U.S. adults aged 50–64 years who currently do not have a risk-based pneumococcal vaccine indication?
- 3. Should PCV21 be recommended for U.S. adults aged 19–49 years who currently do not have a risk-based pneumococcal vaccine indication?

Questions 2 and 3 would result in a new age-based recommendation for these groups.

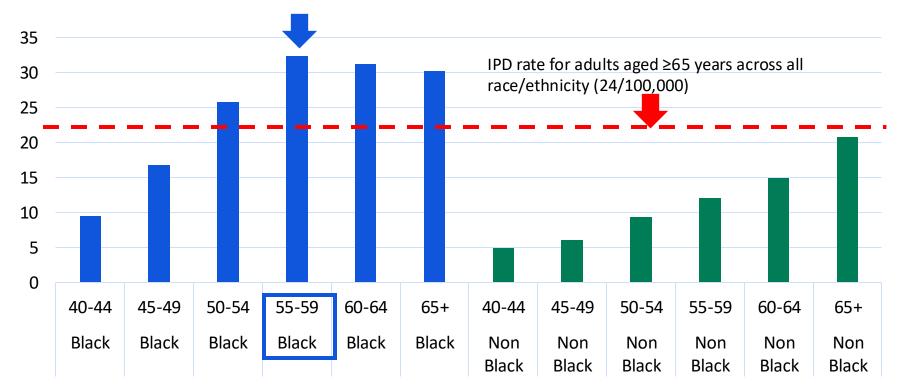
### **Summary of Work Group Discussion**

- The Work Group agreed that available evidence supports PCV21 use for adults currently recommended to receive a PCV
- The Work Group could not reach a consensus on whether the age-based recommendation for PCV21 should be lowered from ≥65 years to ≥50 years
- The Work Group did not support lowering the age-based recommendation for PCV21 to age 19 years
- The majority of Work Group members believed there was insufficient evidence to support lowering the age-based recommendation for currently recommended vaccines

#### **ACIP** recommendation

ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.

# IPD rates in Black adults peak at a younger age compared with Non-Black adults



ABCs 2018 –2019 unpublished data

# **Meningococcal Vaccines**

## Meningococcal Vaccine Work Group: Two Terms of Reference

GSK's MenABCWY Vaccine

Revisiting the adolescent meningococcal vaccine schedule

## **Schedule Options Under Consideration**

Option	ACWY Dose#1	ACWY Dose#2	B Dose#1	B Dose#2						
Current recomm.	11–12 yrs	16 yrs	16 yrs – 23 years ( SCDM	preferred 16–18 yrs)						
1	11–12 yrs	16 yrs	16 yrs	17–18 yrs						
2	11–12 yrs	16 yrs	16 yrs risk-based	17–18 yrs risk-based						
3	No dose	16 yrs	16 yrs risk-based	17–18 yrs risk-based						
4	15 yrs	17–18 yrs	17–18 yrs	17–18 yrs						
5 (ACIP)	No dose	16 yrs	16 yrs	17–18 yrs						
	Proposed recommendations are for routine vaccination unless specifie "risk-based"; option numbers do not represent ordering of preference									

## **Proposed Language**

- Risk group includes adolescents planning to attend college and adolescents in a congregate living setting (e.g., congregate foster care, boarding school, correctional facility, etc.) who are anticipated to remain in this setting long enough to complete the MenB vaccine series
- Any adolescent who desires protection may receive MenB vaccine, even if they are unsure of their future plans which may inform congregate living risk

## **Upcoming ACIP Meetings**

- October 2024
  - -GRADE/EtR
  - Cost-effectiveness analysis
- February 2025
  - Vote (anticipated)

# RSV Vaccines – Maternal/Pediatric

# Two products are recommended to protect infants and young children from RSV lower respiratory tract disease

- RSV prevention in infants during their first RSV season (i.e., aged <8 months)</li>
  - To protect infants in their first season, either maternal RSV vaccination (Abrysvo, Pfizer), or use of nirsevimab (Beyfortus, Sanofi and AstraZeneca) in the infant is recommended to prevent RSV lower respiratory tract disease
  - Administration of both products is not needed for most infants
- Children ages 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab

# Anticipated supply of maternal RSV vaccine and nirsevimab for 2024–2025 RSV season

- For maternal RSV vaccine, no anticipated supply/demand mismatch
- For nirsevimab, limited availability beginning early September, ramping up during September, broadly available by October 1
- Original ACIP recommendations (as published in <u>MMWR</u>) apply for 2024-25 RSV season
- All infants are recommended to be protected by either maternal RSV vaccination or nirsevimab for the 2024-25 RSV season

### Nirsevimab effectiveness

- Effectiveness against RSV-associated hospitalization was 91% in NVSN and 98% in VISION
- Effectiveness against any medically attended RSV-associated ARI episode in NVSN was 89%, and effectiveness against RSV-associated ED visits was 77% in VISION
- CDC platform estimates are consistent with studies in Europe,<sup>1</sup>
- Longer follow up time needed to determine duration of protection
- Limited impact on RSV hospitalization burden, likely because of late administration
  - Substantial decreases in RSV-associated hospitalizations in young infants reported in Spain, Luxembourg, and Italy with early implementation and high coverage<sup>2</sup>

# Recommendations for additional RSV vaccine doses in subsequent pregnancies

- People who received a maternal RSV vaccine during a previous pregnancy are not recommended to receive additional doses during future pregnancies
- Infants born to people who were vaccinated only during a prior pregnancy should receive nirsevimab
- Recommendations can be updated in the future if additional data are available

## **HPV Vaccines**

# **Current HPV vaccination recommendations, United States**

- Routine vaccination
  - Age 11 or 12 years
  - Can be started at age 9 years
- Catch-up vaccination
  - Through age 26 years
- Shared clinical decision-making
  - Age 27–45 years

#### **Number of doses**

2 doses (0, 6-12 months) if starting series before 15<sup>th</sup> birthday

3 doses (0,1-2, 6 months) if starting series on or after 15<sup>th</sup> birthday or if immunocompromising condition

### Topics to be considered by HPV Vaccines Work Group

- Number of doses in the recommended HPV vaccination series.
- Wording of the age for routine vaccination
- Guidance regarding persons in the "shared clinical decision-making" age range (27–45 years)

## **Anthrax Vaccines**

### **Anthrax Vaccine Update**

- July 2023: FDA approved CYFENDUS (anthrax vaccine adsorbed, adjuvanted) for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 - 65 years when administered in conjunction with recommended antibacterial drugs
- This vaccine is comprised of the previously FDA-approved Anthrax Vaccine Adsorbed (AVA) and an additional adjuvant, CpG7909
- Anthrax Vaccine Adsorbed, Adjuvanted vaccine is currently a component of the U.S. government's Strategic National Stockpile for use in an anthrax public health emergency and will replace AVA as it expires
- ACIP will soon convene an Anthrax Vaccine Work Group to review data and provide recommendations for its use to the ACIP committee



## Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention.

