# Update on the June 2024 ACIP meeting

Carolyn B. Bridges, MD, FACP

Director of Adult Immunizations, Immunize.org
Co-Chair, Coding and Billing Task Group and Implementation Task Group, National Adult and Influenza Immunization Summit

Immunize.org

## Disclosures

- I have no conflicts of interest.
- I do NOT intend to discuss an unapproved or investigative use of a commercial product/device in my presentation

Immunize.org

2

## Disclaimer

- The opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the official positions of Immunize.org, or the National Adult and Influenza Immunization Summit

Immunize.org

3

## RSV Vaccines – Adults

Immunize.org

4

# Policy questions

Recommendation for 2023-24 season

- Recommended RSV vaccination of adults 60 years and older based on shared clinical decision making

Policy questions for 2024-25 season

- 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?

Immunize.org

5

# ACIP RSV vaccine recommendations for non-pregnant people beginning 2024-25 season

1. ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccination.[a]
2. ACIP recommends adults 60–74 years of age who are at increased risk of severe RSV disease receive a single dose of RSV vaccination.[a]

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.

Immunize.org

6

## Risk factors for severe respiratory syncytial virus disease among adults aged 60–74 years

- Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])
- Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)
- End-stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance])
- Chronic liver disease (e.g., cirrhosis)
- Chronic hematologic conditions (e.g., sickle cell disease or thalassemia)
- Severe obesity (body mass index ≥40 kg/m$^2$)
- Moderate or severe immune compromise[†]
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk for severe disease due to viral respiratory infection (e.g., frailty,[§] situations in which health care providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging)

* Patient attestation is sufficient evidence

Immunize.org

7

## RSV Vaccines – Maternal/Pediatric

Immunize.org

8

## 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

Immunize.org

9

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

- Original ACIP recommendations (as published in MMWR) apply for 2024-25 RSV season
  - Pregnant people receive a single dose of the Pfizer RSVpreF vaccine (brand name Abrysvo) between 32 and 36 weeks of pregnancy.
  - In most of the continental United States, the vaccine is recommended during RSV season, which is from September through January
- All infants are recommended to be protected by either maternal RSV vaccination or nirsevimab for the 2024-25 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

Immunize.org

10

# COVID-19

Immunize.org

11

## 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

Immunize.org

12

## Key considerations

- 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 people 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 conditions including immunocompromise, and pregnant people to protect themselves and their infants

Immunize.org

13

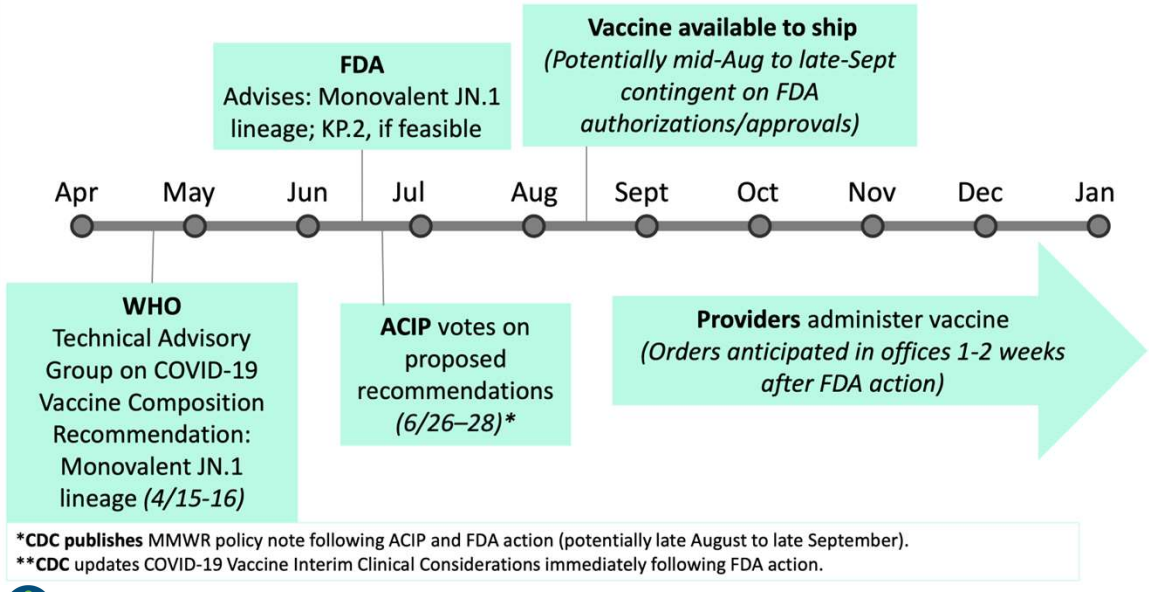
## ACIP recommendation

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

Immunize.org

14

## Prospective 2024 COVID-19 vaccine timeline




*CDC publishes MMWR policy note following ACIP and FDA action (potentially late August to late September).
**CDC updates COVID-19 Vaccine Interim Clinical Considerations immediately following FDA action.

Immunize.org

15

## Influenza

Immunize.org

16

# 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 (new)
  - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

Immunize.org

17

# ACIP recommendation

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

Immunize.org

18

## ACIP recommendation - New

- 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

Immunize.org

19

## Pneumococcal Vaccines

Immunize.org

20

## Adult Pneumococcal Vaccines

| | 1 | 3 | 4 | 5 | 6A | 6B | 7F | 9V | 14 | 18C | 19A | 19F | 23F | 22F | 33F | 8 | 10A | 11A | 12F | 15B | 2 | 9N | 17F | 20 | 15A | 15C | 16F | 23A | 23B | 24F | 31 | 35B |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PCV15** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PCV20** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PPSV23** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PCV21** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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

- **Approved by the FDA for adults aged ≥18 years on June 17, 2024**[1]

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

Immunize.org

1. U.S. FDA Approves CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine) for Prevention of Invasive Pneumococcal Disease and Pneumococcal Pneumonia in Adults - Merck.com

21

## 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 PCV
  - Adults aged 19–64 years with certain underlying conditions or risk factors who have not received a PCV
  - Certain adults who have received PCV13 but have not received PCV20

Immunize.org

22

# ACIP recommendation

## ACIP Pneumococcal Vaccine Recommendations, June 2024

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

Specifically, the ACIP recommended PCV21 for the following populations:

- 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 years who have received a PCV, but have not completed the recommended series
- Shared clinical decision-making for use of a supplemental dose of PCV21 for adults ≥65 years who have completed their vaccine series with both PCV13 and PPSV23

▪ ACIP also considered expanding the age-based recommendation to include adults aged 50-64 years and decided to evaluate this policy question in October 2024.

Immunize.org



## PCV-naïve adults (or adults with unknown history)

| Underlying conditions | Previous vaccination history | Age 19–64 years | Age ≥65 years |
|---|---|---|---|
| None | None | No vaccine recommendation | PCV21 OR PCV20 OR PCV15 → ≥1yr PPSV23* |
| Chronic medical conditions | None | PCV21 OR PCV20 OR PCV15 → ≥8wks† ≥1yr PPSV23* | |
| CSF leak, cochlear implant | None | | |
| Immuno-compromised | None | | |

*If adults previously received PPSV23 before receiving a dose of PCV15, it need not be followed by another dose of PPSV23
†A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/04-Pneumococcal-Kobayashi-508.pdf

Immunize.org

## Shared Clinical Decision-Making Recommendation

### PCV-experienced adults who completed the recommended vaccine series

| Underlying conditions | Age 19–64 years | Age ≥65 years |
|---|---|---|
| None | No vaccine recommendation | PCV13 → (≥8wks*) → PPSV23 (≥1yr); AND (≥5yrs) Shared clinical decision-making → PCV21 OR PCV20 |
| Chronic medical conditions | | |
| CSF leak, cochlear implant | | |
| Immuno-compromised | | |

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

50

Immunize.org https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/04-Pneumococcal-Kobayashi-508.pdf

25

### PCV-experienced adults who have not completed the recommended vaccine series

| Underlying conditions | Age 19–64 years | Age ≥65 years |
|---|---|---|
| None | | PCV13* (≥1yr) → PCV21 OR PCV20 OR PPSV23 |
| Chronic medical conditions | | |
| CSF leak, cochlear implant | PCV13* (≥1yr) → PCV21 OR PCV20<br>PCV13 (≥8wks) → PPSV23 | OR (≥5yrs) → PCV21 OR PCV20 OR PPSV23 |
| Immuno-compromised | PCV13 (≥8wks) → PPSV23 (≥5yrs) → PPSV23 | OR (≥5yrs) → PCV21 OR PCV20 OR PPSV23 |

*includes adults who received PCV15 if PPSV23 not available

52

Immunize.org https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/04-Pneumococcal-Kobayashi-508.pdf

26

Thank you!

Questions?

Immunize.org

27