Updates from the June 2021 ACIP Meeting

This slide set has been prepared by the ACIP Secretariat for use by liaison organizations when providing updates on the ACIP proceedings to their membership. Please do not distribute this presentation without advance permission from the ACIP Secretariat. Final presentations will be posted on the ACIP website: https://www.cdc.gov/vaccines/acip/meetings/index.html

June 2021 ACIP Meeting Agenda

- Dengue Vaccine (Vote)
- Influenza Vaccines (Vote)
- Rabies Vaccines (Vote)
- Pneumococcal Vaccines
- Zoster Vaccines
**Dengue vaccine workgroup timeline**

- **2017**
  - Dengue epi and vaccine development

- **2018**
  - WG on hold
  - Flavivirus WG split
  - Dengue Vaccine Workgroup is formed

- **2019**
  - Phase 3 results
  - Safety & pharmacovigilance
  - GRADE
  - Cost effectiveness
  - Dengue Diagnostics
  - Partially effective vaccines
  - Dengue vaccine in Philippines
  - VRBPAC review
  - FDA approval

- **2020**
  - Vaccine acceptability
  - WHO global position
  - Feasibility
  - Health Equity

- **2021**
  - Dengue IgG test evaluation
  - Evidence to recommendations framework (EtR)
  - Recommendations to ACIP

**Recommendation**

- ACIP recommends 3-doses of Dengvaxia administered 6 months apart at month 0, 6, and 12, in persons 9-16 years of age with a laboratory confirmation of previous dengue infection and living in endemic areas.
FLUCELVAX QUADRIVALENT (ccIIV4) Phase III Immunogenicity & Safety in 6 through 47 months

• SUMMARY
  • ccIIV4 met all of the predefined non-inferiority criteria for immunogenicity as compared to IIV4
  • Immunogenicity data consistent against all four strains
  • ccIIV4 was well tolerated, with similar rates of solicited and unsolicited adverse events between the two vaccination groups, consistent with previously reported data in older children
2021–22 ACIP Influenza Statement

- Core recommendation (unchanged):
  - Annual influenza vaccination is recommended for all persons aged 6 months and older who do not have contraindications.
- Updates:
  - Influenza vaccines expected to be available for the 2021-22 season
  - U.S. influenza vaccine viral composition for the 2021-22 season
  - Change in age indication for Flucelvax Quadrivalent from ≥4 years to ≥2 years
  - Several changes to Timing of Vaccination language
  - Co-administration of influenza and COVID-19 vaccines
  - Contraindications and precautions concerning persons with previous severe allergic reaction to influenza vaccines or their components

Rabies Vaccines
Proposed recommendations for June ACIP vote

- ACIP recommends a 2-dose [0, 7 days] intramuscular rabies vaccine series in immunocompetent persons <18 years of age for whom rabies vaccine pre-exposure prophylaxis (PrEP) is indicated.
- ACIP recommends an intramuscular booster dose of rabies vaccine, as an alternative to a titer check, for immunocompetent persons < 18 years of age who have sustained and elevated risk for only recognized rabies exposures (i.e., those in risk category #3 of rabies PrEP recommendations table*). The booster dose should be administered no sooner than day 21 but no later than 3 years after the 2-dose PrEP series.

*Risk category table in previous slide

Post-exposure prophylaxis (PEP) for persons who have not previously received PEP or PrEP

<table>
<thead>
<tr>
<th>Rabies Vaccine</th>
<th>Rabies Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>Days 3, 7, 14</td>
</tr>
</tbody>
</table>

Human Rabies Immunoglobulin (RIG)
Current and New Pneumococcal Vaccines

- Current
  - 23-valent pneumococcal polysaccharide vaccine (PPSV23), Merck
  - 13-valent pneumococcal conjugate vaccine (PCV13), Pfizer

- New
  - 20-valent pneumococcal conjugate vaccine (PCV20), Pfizer
    - Licensed for use in adults aged ≥18 years on June 8th
  - 15-valent pneumococcal conjugate vaccine (PCV15), Merck
    - BLA filed to FDA, licensure anticipated in July 2021

Overarching Policy Questions Under Consideration by the Work Group

• Should PCV15 be routinely recommended in adults aged ≥50 or ≥65 years?

• Should PCV15 be recommended in younger adults with underlying medical conditions?

• Should PCV20 be routinely recommended in adults aged ≥50 or ≥65 years?

• Should PCV20 be recommended in younger adults with underlying medical conditions?

• Should recommendations be made for PCV15 and PCV20 alone or in series with PPSV23?

Proposed Timeline of ACIP Presentations

June ‘21 ACIP

Presentation on:
• Cost-effectiveness analysis and public health impact
• GRADE/EtR for use of PCV15/20 in older adults

Sept ‘21 ACIP

Presentation on:
• Comparison of cost-effectiveness analyses
• GRADE/EtR for use of PCV15/20 in adults with underlying conditions

October ‘21 ACIP

Vote on recommendations for all newly licensed vaccines
Next Steps

- Additional **cost-effective analyses** underway
- GRADE and EtR for **risk-based recommendation** for younger adults not targeted by the age-based recommendation
  - To be presented at the **September ACIP meeting**

- Refine policy options on **age- and risk- based recommendations** on PCV15 and PCV20 use in adults for a vote at the **October ACIP meeting**
  - PCV15 and PCV20 will be reviewed separately

Zoster Vaccines
Current ACIP Recommendations

- ACIP recommended recombinant zoster vaccine (RZV, Shingrix) in Oct 2017 for use in immunocompetent adults age ≥50 years
- ACIP recommendations include use of RZV in persons
  - Taking low-dose immunosuppressive therapy
  - Anticipating immunosuppression or who have recovered from an immunocompromising illness


IC Populations under Consideration

1. Hematopoietic stem cell transplant (HCT) recipients
2. Patients with hematologic malignancies (HM)
3. Renal or other solid organ transplant (SOT) recipients
4. Patients with solid tumor malignancies (STM)
5. People living with HIV
6. IC populations at increased risk of HZ not covered in groups 1 through 5 (i.e., patients with primary immunodeficiencies, patients with autoimmune conditions, patients taking immunosuppressive medications)
**Policy question:** “Should vaccination with RZV be recommended for immunocompromised adults 19 years of age and older?”

- **Population:** IC adults ≥19 years of age; split into two parts (19–49 years, ≥50 years)
- **Intervention:** RZV, 2 doses at least 4 weeks apart
- **Comparison:** No vaccine
- **Outcomes**

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Harms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Prevent HZ</td>
</tr>
<tr>
<td>Important</td>
<td>Prevent PHN</td>
</tr>
<tr>
<td></td>
<td>Prevent HZ-related hospitalization</td>
</tr>
<tr>
<td></td>
<td>Immune-mediated disease</td>
</tr>
<tr>
<td></td>
<td>Reactogenicity (Grade 3)</td>
</tr>
<tr>
<td></td>
<td>Graft versus host disease (HCT)</td>
</tr>
<tr>
<td></td>
<td>Graft rejection (SOT)</td>
</tr>
</tbody>
</table>

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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

Photographs and images included in this presentation are licensed solely for CDC/NCIRD online and presentation use. No rights are implied or extended for use in printing or any use by other CDC CIOs or any external audiences.