Summary and Work Group Considerations

Lisa Grohskopf, MD, MPH
Influenza Division, NCIRD, CDC

Advisory Committee on Immunization Practices
February 26, 2020
Acknowledgments

**Influenza Division**
Elif Alyanak
Lenee Blanton
Lynnette Brammer
Joe Bresee
Alicia Budd
Jessie Chung
Scott Epperson
Jill Ferdinands
Brendan Flannery
Alicia Fry
Dan Jernigan
Krista Kniss
Manish Patel
Melissa Rolfes
Jerry Tokars
Tim Uyeki

**Immunization Safety Office**
Karen Broder
Frank Destefano
Penina Haber
Tom Shimabukuro

**Immunization Services Division**
Sam Graitcer
Andrew Kroger
Amy Parker Fiebelkorn
Jeanne Santoli

Rebecca Morgan
Influenza Vaccine Distribution Update
Cumulative doses of influenza vaccines distributed by month, by season:
2016-'17 - 2019-'20
Influenza Vaccines for Older Adults—WG Considerations
Abbreviations

IIV Inactivated Influenza Vaccine
ccIIV Cell culture based Inactivated Influenza Vaccine
aIIV Adjuvanted Inactivated Influenza Vaccine
HD-IIV High-Dose Inactivated Influenza Vaccine

RIV Recombinant Influenza Vaccine

LAIV Live Attenuated Influenza Vaccine

Numbers indicate the number of influenza virus antigens:
3 for trivalent: an A(H1N1), an A(H3N2), and one B (from one lineage)
4 for quadrivalent: an A(H1N1), an A(H3N2), and two Bs (one from each lineage)
## U.S.-Licensed Influenza Vaccines Available for 2019-20

Available vaccines by FDA-licensed age indication:

<table>
<thead>
<tr>
<th>Vaccine type</th>
<th>6 through 23 mos</th>
<th>2 through 3 yrs</th>
<th>4 through 17 yrs</th>
<th>18 through 49 yrs</th>
<th>50 through 64 yrs</th>
<th>≥65 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIV4s (egg-based)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Afluria Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluarix Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FluLaval Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIV4 (cell-based)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIV4 (recombinant)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flucelvax Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flublok Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjuvant IIV3 (egg-based)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone High-dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAIV4 (egg-based)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FluMist Quadrivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- ACIP recommends that a licensed, age-appropriate influenza vaccine should be used.
- No preferential recommendations are made for any specific influenza vaccine for any age group, where there is more than one that is appropriate.
Whether the relative benefits and harms of HD-IIV, aIIV, and RIV, as compared with one another and with other influenza vaccines, favor the use of any one or more of these vaccines over other age-appropriate influenza vaccines for persons ≥65 years of age.
Current Systematic Review/Meta-analysis—PICO (1)

**Population:** Adults aged ≥65 years

**Interventions:** Trivalent/quadrivalent high dose IIV, adjuvanted IIV, or RIV  
(U.S.-licensed, or similar in formulation/manufacture to U.S.-licensed)

**Comparators:** Other trivalent or quadrivalent influenza vaccine  
(U.S.-licensed, or similar in formulation/manufacture to U.S.-licensed)  
Non-influenza control vaccine  
Placebo  
No vaccine
Primary Outcomes: Efficacy/Effectiveness
- All influenza -- A and B
- Influenza-associated outpatient/emergency visits
- Influenza-associated hospitalizations
- Influenza-associated deaths

Safety
- Any systemic adverse event (grade ≥3)
- Any injection site adverse event (grade ≥3)
- Any serious adverse event (SAE)
- Guillain-Barre syndrome
Secondary Outcomes:

- To the extent data are available, the following will be summarized:
  - Influenza-associated outpatient/emergency visits, hospitalizations, and deaths, stratified by influenza virus type/subtype
  - Serious adverse events (SAEs) judged to be related to study intervention
Inclusion/Exclusion Criteria

- Peer-reviewed literature; no language restriction
- Publication dates from 1990 forward
- Main inclusion criteria:
  - Randomized studies (individually- and cluster-randomized designs)
  - Retrospective case-control studies (traditional and test-negative designs)
  - Retrospective and prospective cohort studies.
- Main exclusion criteria:
  - Data involving influenza vaccines not licensed in the United States for persons ≥65 years of age
  - Studies/data for which the entire population falls outside age range of interest
  - Studies/data assessing monovalent or bivalent vaccines
  - Case series, case reports, registry reports without comparator or denominator information
  - Animal studies
  - Interim reports superseded by final reports
Thank you