Influenza Summary and WG Considerations

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2017-18 ACIP Influenza Recommendations

- No new policy language proposed for consideration at this meeting.

- 2017-18 Statement will reiterate core recommendation that annual influenza vaccination is recommended for all persons aged 6 months and older who do not have contraindications.

Work Group Considerations:
Afluria (IIV3) and Afluria Quadrivalent (IIV4)

- Presentations on Afluria Quadrivalent pre-licensure data for adults (presented to ACIP in October) and children age ≥5 years

- Presentation summarizing safety investigation into etiology of febrile seizures and reactions associated with 2010 Southern Hemisphere trivalent formulation

- Work Group proposed no change in language for Afluria trivalent; awaits licensure of the quadrivalent formulation for age ≥5 years

Work Group Considerations:

Fluzone High-Dose, Fluad, and Flublok for Older Adults

- Presentation of Gravenstein long-term care facility data
- Currently, two vaccines are licensed specifically for age ≥65 years. Data heard by ACIP include:
  - Fluzone High-Dose (high-dose IIV3, Sanofi Pasteur)
    - Superior VE to standard-dose IIV3 against protocol-defined ILI associated with lab-confirmed influenza in a two-season RCT of ~32,000 persons age ≥65 years
  - Fluad (adjuvanted IIV3, Seqirus)
    - Superior VE to unadjuvanted IIV3 against lab-confirmed influenza in an analysis of 227 participants in a one-season observational study of persons age ≥65 years
- ACIP has previously heard data from a 2014-15 season randomized trial of Flublok Quadrivalent (RIV4, Protein Sciences) noting superiority over IIV4 for persons age ≥50 years
- No direct comparisons of these vaccines with one another
- ACIP currently expresses no preference for one vaccine over another
- WG proposed no change in language, and looks forward to further discussion of efficacy and effectiveness data for these vaccines in this high-risk population
- Data for vaccines for this population will be summarized in upcoming 2017-18 ACIP Influenza Statement

Influenza Vaccine Coverage Among Children

Preliminary Estimates, 2016-17—NIS-Flu

- CDC has updated early season influenza vaccination coverage estimates (NIS-Flu) to evaluate potential impact of the recommendation to not use LAIV for the 2016-17 season.
- Preliminary estimates reflecting reported vaccinations received by end of December, 2016.
  - Coverage among children ages 6 months–17 years increased from 37% by early November to 50% by end of December.
  - Coverage through December (50%) was similar to coverage through December last season (51%).
  - By age group, no statistically significant differences for 2016-17 compared to 2015-16 season (percentage point differences ranged from 2.7% for ages 13-17 years to -2.8% for ages 5-12 years).
- As in past seasons, coverage was higher in younger children: 66% for ages 6-23 months, 56% for ages 2-4 years, 50% for ages 5-12 years, and 40% for ages 13-17 years.
- In past seasons, influenza vaccination of children continued to be reported past December; for 2015-16, coverage increased from 52% by the end of December 2015 to 59% by end of May 2016.

Influenza Division Activities

Vaccine Effectiveness

- Ongoing evaluation of vaccine effectiveness via the U.S. Influenza Vaccine Effectiveness Network
  - Intraseasonal waning and decision tree analysis regarding timing of vaccination
  - Research studies ongoing to assess immunologic effects of repeat vaccination

- LAIV Studies
  - Systematic Review of literature and meta-analysis of efficacy and effectiveness of LAIV since 2010-11
  - Combined US individual patient-level LAIV effectiveness analysis (CDC, DoD, MedImmune)

- Production and publication of annual ACIP influenza statement

Work Group Considerations:
FluMist (LAIV)

- Best evidence to support recommendation for use would be effectiveness data for LAIV (containing a new H1N1 component) against H1N1 viruses

- Anticipated data timelines:
  - 2016-17 effectiveness data (H3N2) from U.S., U.K, Finland--June 2017
  - Efficacy (H3N2) from Japan, U.S. pediatric shedding/immunogenicity--October 2017

- Will not be able to assess effectiveness against H1N1 from current season's data

- Cannot predict when next H1N1-predominant season will occur (therefore, possibly several years before H1N1-specific effectiveness or efficacy data are available)

Work Group Considerations:

FluMist (continued)

- In the absence of effectiveness/efficacy data for FluMist with a new H1N1 component, the following would be reassuring:
  - Demonstration that the new virus exhibits improved fitness in animals (ferrets), and particularly in human shedding and immunogenicity studies,
  - Demonstration that performance (e.g., replicative fitness) is similar to that of pre-pandemic H1N1 viruses (which were demonstrated to be effective)
- A caveat--there is no adequate correlate of protection for LAIV against influenza viruses
  - Shedding and antibody levels do not always correlate with effectiveness
  - Shedding is an indication of replicative fitness and vaccine “take”; however, lack of shedding has not always correlated with poor effectiveness
  - Therefore, there is inherent difficulty in interpreting a negative (poor shedding) result
- However, human shedding and antibody (immunogenicity) data (anticipated October 2017) are probably the most constructive data that can be collected within 1-2 season timeframe

Work Group Considerations:
FluMist (continued)

Does the ACIP feel these data will be sufficient to re-consider whether to recommend LAIV?

For more information, contact CDC
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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.