LAIV Effectiveness: WG Discussion

- Influenza WG reviewed data presented by CDC and MedImmune.
- Substantial concern about the effectiveness of LAIV in recent seasons.
- Issues discussed:
  - No new data expected prior to next season
  - Variability in point estimates of VE for 2016-17, but U.S. sources consistently indicate no significant effectiveness of LAIV against (H1N1)pdm09 (while IIV was effective)
  - Cause of low VE not completely elucidated
    - Not feasible to address for the 2016-17 season
    - H1N1 construct in the 2016-17 vaccine same as that for 2015-16
  - Uncertainty regarding potential effectiveness of LAIV for 2016-17
    - Effectiveness of quadrivalent LAIV against H3N2 in a season with good match against circulating viruses unknown

Proposed Recommendations 2016-17 Influenza Season

Lisa Grohskopf, MD

Influenza Division, CDC

Advisory Committee on Immunization Practices

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- Reiteration of core recommendation that annual influenza vaccination is recommended for all persons of persons 6 months of age and older.
- Minor change in timing of vaccination language.
- Changes to egg allergy recommendations, allowing use of LAIV and removing the 30 minute post-vaccination waiting period.

New and Upcoming Potential Licensures

- New Licensures (listed in the Available Products table):
  - Fluad (MF59-adjuvanted inactivated influenza vaccine, trivalent; Seqirus) for persons ≥65 years.
  - Flucelvax Quadrivalent (cell culture-based inactivated influenza vaccine, quadrivalent); Seqirus) for persons ≥4 years.

- Potential upcoming licensures (will be acceptable options to existing products for appropriate age groups if licensed):
  - Flublok Quadrivalent (recombinant influenza vaccine, quadrivalent; Protein Sciences) for persons ≥18 years.
  - Flulaval Quadrivalent (inactivated influenza vaccine, quadrivalent); GSK) for persons ≥6 months (0.5cc dose).

LAIV: Potential Impact of Policy Change

- Possible challenges for vaccine supply and availability if LAIV no longer recommended or providers elect to stock other vaccines.
- May disrupt school-located vaccine programs that primarily use LAIV.
- Decrease in LAIV use may preclude evaluation of vaccine effectiveness in future seasons.
- Potential for confusion in program implementation if ACIP/CDC and AAP recommendations not harmonized.

Option A: Interim Recommendation for Limited Use of LAIV

- "In light of the evidence for poor effectiveness of LAIV in the U.S. over the last three influenza seasons (2013-14 through 2015-16), for the 2016-17 season, ACIP makes the interim recommendation that LAIV should not be routinely used. Use of LAIV may be considered in certain circumstances, such as..."
- Examples (clinical guidance to be developed by CDC):
  - Refusal of injectable vaccine.
  - Shortage of age-appropriate IIV or RIV.
  - School based programs with no alternative vaccine.

Option B: Interim Recommendation That LAIV Should Not Be Used

- "In light of the evidence for poor effectiveness of LAIV in the U.S. over the last three influenza seasons (2013-14 through 2015-16), for the 2016-17 season, ACIP makes the interim recommendation that LAIV should not be used."