Flu Summit 2015

Science Policy Partnership
National Adult and Influenza Summit, Atlanta, GA

Agenda

- Science - FluMist Quadrivalent® (Influenza Vaccine Live, Intranasal)
- Policy
  - Recommendations
  - Shaping the Landscape
- Partnerships
- What to Expect for 2015/16
Like Many Routine Vaccines, FluMist Quadrivalent is a Live Attenuated Vaccine

- Cold-adapted (ca) (A)
  Replicates efficiently only in cooler areas of the nasopharynx at temperatures that are restrictive for replication of many wild-type influenza viruses.

- Temperature sensitive (ts) (B)
  Does not replicate efficiently in warmer areas of the lower respiratory tract where influenza viruses typically replicate

- Attenuated (att)
  Disease properties modified so as to not cause influenza-like illness

- Quadrivalent formulation helps to offer protection against four influenza virus strains in the vaccine

FluMist® (Influenza Vaccine Live, Intranasal) Doses Distributed (includes quadrivalent distribution)

First fully converted quadrivalent flu vaccine

Universal immunization recommendation and implementation

Please see Important Safety Information on Slide 10
Changing the Landscape

• First and only intranasal influenza vaccine in the United States

• More than 2 million doses FluMist Quadrivalent administered in a school-located vaccine clinic (SLVC) setting since 2010 (excludes H1N1 pandemic vaccine)
  • SchoolMist programs commenced 2009/10
  • Public and private doses
  • Includes FMQ vaccine in CDC billables projects
  • 8.8% of all influenza doses administered in an SLVC

• Direct-to-Consumer campaigns across the nation
  • Encourage the entire family to seek influenza immunization
  • Directs parents to the healthcare provider

• Focus on retail pharmacies to increase vaccine choice

Please see Important Safety Information on Slide 10

1. MedImmune Data on File

We Are Not Done – So Much More to Do

Challenges of last season (H3N2 vaccine effectiveness) did not advance public confidence in influenza immunization

We recognize that it takes more than just a routine recommendation to increase immunization rates

Generous vaccine supply yet demand is not increasing

Harmony and alignment on the need for an annual flu vaccine must be consistent across multiple organizations
The Tipping Point - Partnerships

- Partnerships are needed to maintain and increase immunization rates
- The Flu Summit remains the driving force

What to Expect for 2015/16 Season

- Over 16 million doses for the 2015/16 season
- Our commitment to shipping as soon as possible remains. Additional information on shipping will be communicated prior to season start to ensure HCPs can plan their vaccination efforts accordingly.
- New packaging
New Packaging

- Environmentally safer by eliminating the use of Tyvek® and Polyethylene Terephthalate Glycol (PETG) Trays
- Reduces 10-carton volume by ~18%
- Dimensions are available upon request

Important Safety Information

- LAIV4 is a vaccine indicated for active immunization of persons 2-49 years of age for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. LAIV4 is for intranasal administration only.
- LAIV4 is contraindicated in persons who have had a severe allergic reaction to any vaccine component including egg protein or after a previous dose of any influenza vaccine, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.
- In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received LAIV3. Children <5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following LAIV4 administration. LAIV4 has not been studied in persons with severe asthma or active wheezing.
- If Guillain Barré syndrome has occurred within 6 weeks of any prior influenza vaccination, the decision to give LAIV4 should be based on careful consideration of the potential benefits and risks. LAIV4 has not been studied in immunocompromised persons. The safety of LAIV4 in individuals with underlying medical conditions predisposing them to wild-type influenza infection complications has not been established. LAIV4 may not protect all individuals receiving the vaccine.
- The most common solicited adverse reactions (occurring ≥10% in vaccine recipients and at least 5% greater than in placebo) reported after LAIV3 were runny nose or nasal congestion in all persons 2-49 years, fever >100°F in children 2-6 years, and sore throat in adults 18-49 years. Among children 2-17 years who received LAIV4, 32% reported runny nose or nasal congestion and 7% reported fever >100°F. Among adults 18-49 years who received LAIV4, 44% reported runny nose or nasal congestion and 19% reported sore throat.

- Please see complete Prescribing Information, including Patient Information
Influenza Vaccines Available in the United States

**FluMist®**
(Influenza Virus Vaccine Live, Intranasal)*
- Attenuated vaccine with multiple antigens\(^1,2\)

**Inactivated Influenza Vaccine (Intramuscular)**
- HA is the only standardized component; other antigens may be present\(^3,4\)