MedImmune

Specialty Care Division of AstraZeneca

# Flu – Use Your Nose

Heather Richmond
CDC/DoD Liaison

Flu Summit

May 15, 2014



## LAIV Presentation Topics

- Supply
- Distribution
- Replacement
- Areas of Interest

## Seasonal Live Attenuated Influenza Vaccine (QLAIV)

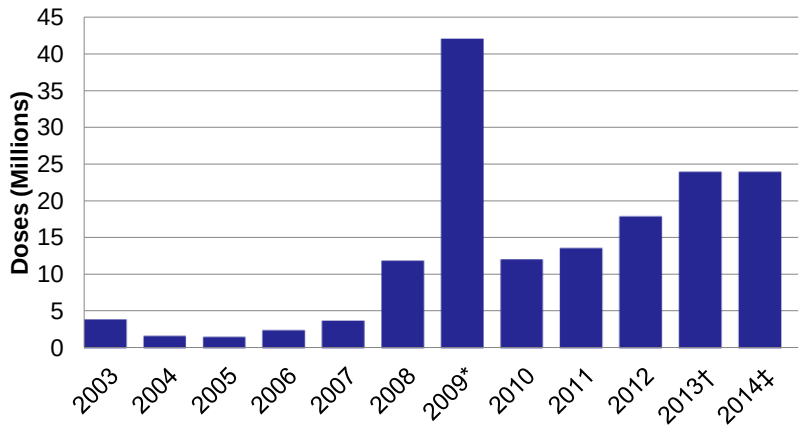
- **Approved** in US for eligible individuals 2–49 years of age
- **Contains** $10^{6.5\text{-}7.5}$ FFU* of each strain per dose
  - Quadrivalent in US starting in 2013-14 season
- **Contains** no preservatives or adjuvants
- **Stored** at 2-8°C (refrigerator)
- **Administered** as nasal spray
- **>75 million doses** distributed since 2003
- Available only in quadrivalent formulation

*Fluorescent focus units



**Supply**

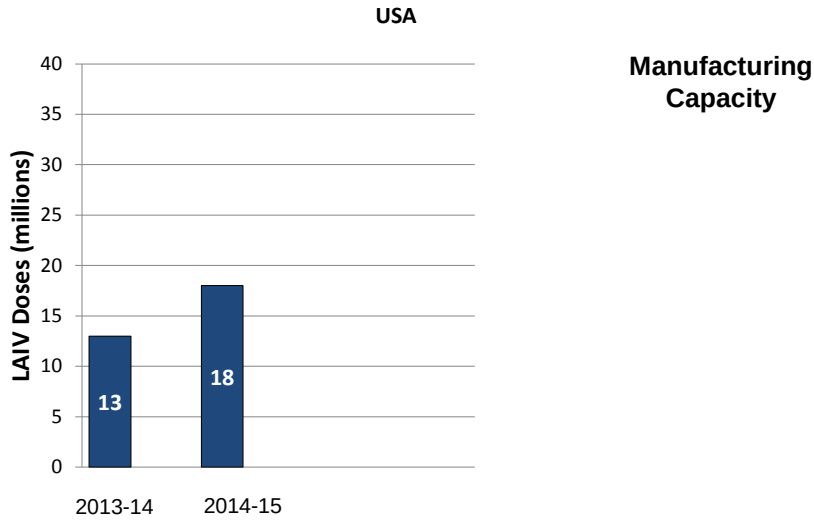
## Doses of LAIV Produced or Distributed




* 2009-10 doses produced includes monovalent pandemic H1N1 vaccine doses.
† 20013-14 doses distributed as of Dec 6 2013.
‡ 20014-15 doses produced is tentative forecast number.

Supply

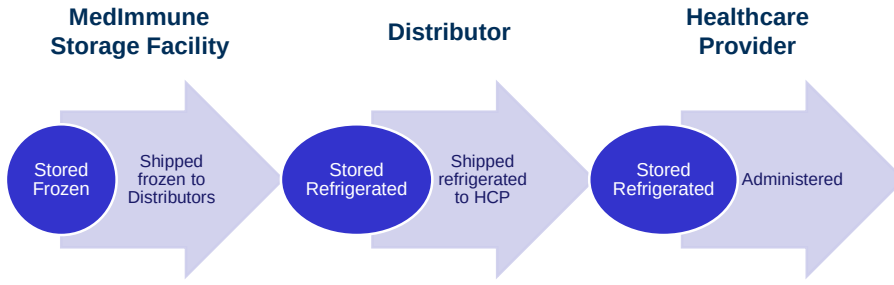
## Current and Projected LAIV Manufacturing Capacity Compared to Potential Demand






Distribution

## LAIV US Distribution and Expiry Dating




Total of 18 weeks of refrigerated storage before expiry

- CDC VFC contract specifies delivery of LAIV with at least 16 weeks (4 months) of remaining shelf life
- Private HCP contracts rely on distributors to manage remaining shelf life

Toback SL, et al., 2011; *J Pediatr Nursing* 27:163-167.

Replacement

# MedImmune Replacement Program for Expiring Doses

- Eligibility: Unused doses expiring on or before January 31, 2015
- Process
  - Within 2 weeks of expiration, HCP notifies distributor of replacement needs
  - Per distributor instructions, HCP ships doses back to distributor*
  - Distributor ships replacement doses with later expiry dating
    - E.g., Replacement doses provided in January can be used during March/April/May
- Information on Replacement Program
  - Contained in every LAIV shipment to private HCPs
  - Communicated to VFC grantees
  - Posted on CDC website
  - Posted on the product website

* Claims for replacement doses are made in multiples of 10 doses.



# 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, gentamicin, gelatin and arginine 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

## New Landscape

- Parents are the gatekeepers of health for their families – QLAIV is an option for those eligible between the ages 2 – 49 years
- Place of flu vaccination has shifted with the implementation of the universal recommendations
  - CDC reports that pharmacies, workplace clinics and school-located vaccine clinics are growing for influenza vaccine administration
  - Pharmacies/retail stores are the second largest adult flu immunizers and growing for pediatrics
- MedImmune has partnered with pharmacies and retail to promote awareness of flu vaccine for families

Place of flu vaccination (%) for children and adults, National Immunization Survey and National Internet Flu Survey, early 2013-14 season



## Empowering the Gatekeeper

- Connect with the Family Gatekeeper
  - Social media 2.0 facebook twitter
- Work with Community Advocates
  - Vaccination events, parenting book


- 2013-14 spokesperson for flu vaccine
  - Tia Mowry

## Things People Put in Their Nose