FluMist® Update
(Influenza Virus Vaccine Live, Intranasal)

National Influenza Vaccine Summit

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June 29, 2009
Dallas, TX

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2009-10 Seasonal Vaccine Selection and Production

19 Strains from CDC: 4 H1N1, 5 H3N2, 7 B Victoria, 3 B Yamagata

12 LAIV Candidates Made: 3 H1N1, 3 H3N2, 4 B Victoria, 2 B Yamagata

3 LAIV Strains Approved: A/South Dakota/6/2007 (H1N1)
A/Uruguay/617/07 (H3N2)
B/Brisbane/60/2008 (Victoria Lineage)

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**FluMist® for the 2009-10 Season**

- **Planned supply:** 10 - 11 million doses
- **Shipping expected to begin in August**
- **Customers have choice of distributor**
  - McKesson Medical-Surgical
  - Besse
  - ASD
  - Moore Medical

- **One new strain in vaccine**
  - Production is going well
  - All strains produced using reverse genetics

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**H1N1 LAIV**

- An initial order of $90M of vaccine has been placed, with the potential for additional orders.
  - H1N1 LAIV project has been funded in whole or in part with Federal Funds from the HHS/ASPR/BARDA, under Contract No. 100200900002I

- **H1N1 LAIV is same as seasonal FluMist vaccine, except is monovalent**
  - 0.2 mL/dose (0.1 mL in each nostril) delivered by nasal spray
  - Produced in eggs
  - Contains no preservatives or adjuvants
  - Dose is fixed at $10^{7.0}\pm0.5$ FFU/strain

- **Clinical studies planned**
  - Two concurrent placebo-controlled studies in children aged 2 – 17 years and adults aged 18 – 49 years
  - 2-dose schedule delivered 4 weeks apart
  - Objectives
    - Demonstrate attenuation (assess solicited symptoms and adverse events)
    - Assess serum immune responses after each dose (no known correlate of protection)

- **If yield is consistent with that for seasonal strains, can make ~ 35 M doses**
Activities to Support Awareness of Influenza Vaccination and New Pediatric Recommendations

‘Choose Your Administration’
Promoting Dialogue on Flu Immunization

Goals:
• Urge eligible adults and families to choose or “elect” to get a flu vaccination
• Encourage early vaccination

Implementation:
Connect immunization messages with high level of interest and enthusiasm in the U.S. election:
• Media/Blogger Relations
• Web site promotion
• Presence at Democratic and Republican National Conventions
‘Choose Your Administration’

Impact

Discussion of flu vaccination earlier in the season

70+ Media Interviews, including two live national hits on political programs
More than 30,000 CHOOSE buttons distributed

‘Choose Your Administration’

Harris Survey

- ‘What can you do to help protect your child against influenza?’
  - 85% agree that getting required immunizations is very important
  - 82% are aware that they can get their children vaccinated against influenza
  - 44% report ever having their child vaccinated against influenza

- ‘What can you do to protect your child against influenza?’
  - Parents of children aged 8 – 17 years ranked vaccination 6th among 7 options

On-line survey of 952 parents and 875 children

89% 81% 80% 69% 58% 56% 55%

Wash Hands  Get Enough Sleep  Eat Healthy  Avoid People That are Sick  Take Vitamins  Get a Flu Vaccine Annually  Dress for the Weather

Proprietary
Raising Awareness Among Moms About Flu Vaccination

Sign-up today to receive an alert at time of campaign launch
**Consumer Education**

- Sponsored AAP Public Service Announcement on the new pediatric influenza vaccine recommendations
- Distributed the CDC Public Service Announcement “Why Flu Vaccination Matters: Personal Stories from Families Affected by Influenza” to pediatricians and family physicians

**School Programs**

- Expanded CDC/ACIP flu recommendations in 2009-2010 increase the number of children recommended for vaccination by approximately 30 million
- MedImmune has demonstrated a commitment to school flu vaccination over the past 7 years

*CDC/ACIP = Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices*
Teach Flu a Lesson Objective

- Encourage schools/school nurses/early childhood professionals to begin implementing school influenza vaccination programs

Target audiences for the Teach Flu a Lesson initiative include:
- Health Departments
- Nurses
- Parent Groups
- Teachers

The Teach Flu a Lesson initiative will provide guidelines, tips and customizable tools to help plan and implement flu vaccination programs in schools
- Advertising and Direct Mail
- www.teachflualesson.com
- Vaccination Connections
PIC Study Objectives and Design

**Objectives**
- Describe vaccine coverage of children aged = 18 years in pediatricians’ offices
- Examine correlations between in-office influenza vaccine uptake and the use of various methods to increase vaccine coverage

**Study design**
- Prospective, observational study conducted during two influenza seasons (2007-09)
- Geographically balanced sample of US outpatient pediatric offices
  - Year 1: 44 offices (>280,000 children)
  - Year 2: 89 offices (>498,000 children)

**Study endpoints**
- Description of office behaviors
- Influenza vaccination coverage in children aged = 18 years by age group
- Compliance with the recommended 2-dose regimen
- Correlation of office vaccination–related attitudes and activities with vaccine uptake

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Influenza Vaccine Administered by Type to Children Aged 2 – 18 Years


PIC Study Results: Timing of Vaccination

Number of Doses Administered by ½-Month Intervals
VFC = Vaccine for Children (bottom line); nVFC = non-VFC (top line)
PIC Study Conclusions

- **Coverage**: Pediatric practices may be able to increase in-office vaccination by offering vaccines for a longer period of time
  - Should better utilize months before October and after December
  - Larger practices may be at a disadvantage in achieving high rates

- **Compliance**: VFC vaccine administration was delayed compared to privately purchased vaccine
  - May explain lower 2-dose compliance among children receiving VFC vaccine
  - Efforts should be taken to utilize VFC vaccine as soon as possible

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Important Safety Information

- **FluMist** (Influenza Virus Vaccine Live, Intranasal) is indicated for active immunization of non-pregnant persons aged 2 - 49 years.
  - FluMist is not indicated for children aged <24 months, children aged <5 years with recurrent wheeze, persons with underlying medical conditions predisposing them to complications associated with influenza, immunocompromised persons, persons with history of GBS.

- **FluMist contraindicated for**:
  - Persons with history of hypersensitivity to eggs, gentamicin, gelatin or arginine or with life-threatening reactions to previous influenza vaccinations
  - Children and adolescents receiving aspirin or aspirin-containing therapy.

- Most common adverse reactions are runny nose or nasal congestion in recipients of all ages, fever >100°F in children 2-6 years of age, and sore throat in adults.

- **Complete Prescribing Information** is available upon request or at [www.flumist.com](http://www.flumist.com)