FluMist® Update
(Influenza Vaccine Live, Intranasal)

National Influenza Vaccine Summit

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May 17, 2010
Phoenix, AZ

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2009-10 Seasonal FluMist Experience

- Approximately 10.7 M doses produced
  - All doses were ordered
  - All orders were fulfilled

- Shipping started July 28, 2009
  - Shipping targeted to summer months to increase vaccination opportunities at back-to-school check-ups, sports physicals, etc.

- Significant use of FluMist by children (non-VFC doses)
  - 34% of all children vaccinated by all providers*
  - 38% of all children vaccinated in pediatrician offices*

* Surveillance Data, Inc., US Provider Insurance Claims Data
2009 H1N1 Pandemic LAIV Timeline

- LAIV was first pandemic vaccine shipped to the US government
  - Provided ~25% of US doses
  - Significant use by children

Central Texas School-Located Influenza Vaccine Trial:
2009 Interim Report

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Baylor College of Medicine

W Paul Glezen, MD
Baylor College of Medicine

Manjusha J Gaglani, MD
Scott & White Memorial Hospital and Clinic
Central Texas Trial

- Goal is to reduce overall influenza morbidity in intervention communities by
  - Providing direct protection and improved vaccination coverage in school-aged children
  - Providing indirect protection to others residing in intervention communities.
- Impact is measured by comparison to neighboring control communities.
- Multi-year trial in school-aged children
  - Clinic-based from 1998 – 2002
  - Outreach-based from 2003 – 2006
  - School-based from 2007 to present.
- Investigator-initiated trial funded by MedImmune (DMID/NIAID/NIH funded from 1998-2007).

Study Design 2009

- Community-based, school-located, open-label, non-randomized trial.
- Scott & White Clinic is major medical provider in both intervention and comparison cities.

### Vaccination

- **Seasonal LAIV and TIV**
  - Aug 25 to Sep 22

- **H1N1 m LAIV only**
  - Oct 8 to Nov 5

- **H1N1 m LAIV and m TIV**
  - Nov 9 to Dec 11

### Influenza Surveillance (Aug 25 – Dec 12)
Methods

- Vaccination of children in schools in intervention cities
  - LAIV: healthy children 4 years old and adults <50 years old
  - TIV: high-risk children 4 years old, adults ≥50 years, and anyone who preferred TIV

- Surveillance in intervention and comparison cities
  - Cultures were obtained from any person seeking medical attention for febrile respiratory illness
  - Influenza isolated by culture and identified by RT-PCR

- Outcome
  - Effectiveness against influenza A culture-positive febrile medically attended acute respiratory illness (fMAARI)
  - Age-specific fMAARI rates in the intervention and comparison cities, irrespective of vaccination status.

Vaccination Coverage in School-Aged Children in Intervention Cities

- Seasonal Vaccines: 55% coverage (59% elementary, 51% middles & 40% high schools)
  - 13,107 children were vaccinated
    - 72% received LAIV
    - 28% received TIV

- Pandemic Vaccines: 36% coverage (42% elementary, 32% middles & 19% high schools)
  - 8,670 children were vaccinated
    - 90% received mLAIV
    - 10% received mTIV
H1N1 Illness In Intervention and Comparison Cities

Pandemic Vaccination Period Sep 23 – Dec 12, 2009

<table>
<thead>
<tr>
<th>Age</th>
<th>Temple-Belton (intervention cities)</th>
<th>Waco, Bryan &amp; College Station (comparison cities)</th>
<th>Chi square with Yates correction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No.</td>
<td>No. of SOIV Infections (%)</td>
<td>Total No.</td>
</tr>
<tr>
<td>&lt; 4</td>
<td>103</td>
<td>33 (32%)</td>
<td>62</td>
</tr>
<tr>
<td>4 - 9</td>
<td>147</td>
<td>57 (38.8%)</td>
<td>99</td>
</tr>
<tr>
<td>10 - 18</td>
<td>131</td>
<td>61 (46.6%)</td>
<td>95</td>
</tr>
<tr>
<td>19 - 49</td>
<td>118</td>
<td>21 (17.8%)</td>
<td>157</td>
</tr>
<tr>
<td>50 - 64</td>
<td>30</td>
<td>9 (30%)</td>
<td>27</td>
</tr>
<tr>
<td>&gt; 65</td>
<td>7</td>
<td>0 (0%)</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>536</td>
<td>181 (33.8%)</td>
<td>446</td>
</tr>
</tbody>
</table>

Summary

- Vaccination of age-eligible children in public, private and home schools:
  - ~55% coverage with seasonal vaccines
  - ~36% coverage with pandemic vaccines

- Pandemic vaccines, but not seasonal vaccines, were associated with significant overall effectiveness in all age groups against culture positive 2009 H1N1 influenza A illness in the intervention communities compared to comparison communities.
FluMist for the 2010-11 Season

- Planned supply: ~16 million doses
- Shipping expected to begin in July – August timeframe
- Customers have choice of distributor
  - McKesson Medical-Surgical
  - Besse
  - ASD
  - Moore Medical
- Trivalent seasonal FluMist for 2010-11
  - Trivalent:
    - A/California/7/2009 H1N1 (pandemic)
    - A/Perth/16/2009 H3N2 (new)
    - B/Brisbane/60/2008 (retained)
  - Production is going well
  - All strains produced using reverse genetics

Production of A/Perth/16/2009 H3N2 Seed

9 H3N2 Strains from CDC:


H3N2 Seed: A/Perth/16/2009
Plans for 2010-11 Season

- Education
- Motivation

Health Care Provider Education

- Webinar to Dispel Top Five Myths About Live Attenuated Influenza Vaccine
- DVD Administration video on www.flumist.com
Motivation and Public Health Support

Public Vaccination Options (VFC, VFA)

School Vaccination Programs

Thank You!