



FluMist® Update (Influenza Vaccine Live, Intranasal)

National Influenza Vaccine Summit

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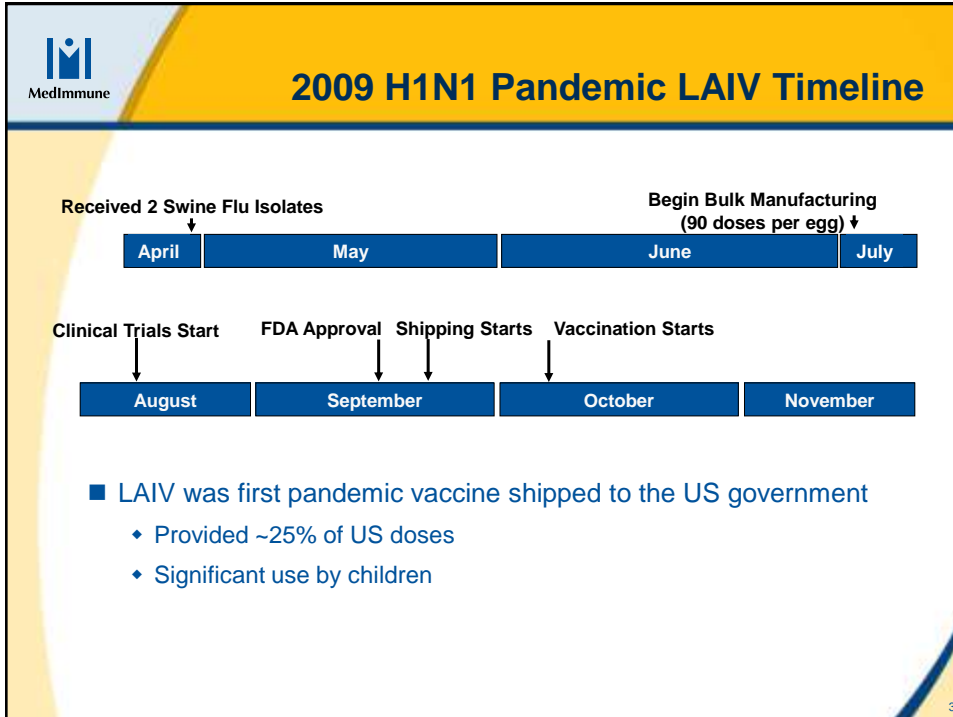


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2009-10 Seasonal FluMist Experience

- 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

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

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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).

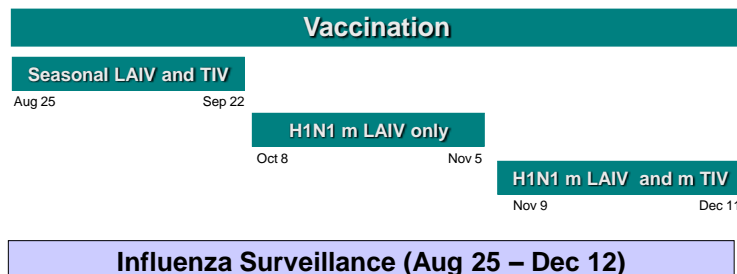
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Study Design 2009



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



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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.

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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 mLAIIV
 - 10% received mTIV

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H1N1 Illness In Intervention and Comparison Cities



Pandemic Vaccination Period Sep 23 – Dec 12, 2009

Age	Temple-Belton (intervention cities)		Waco, Bryan & College Station (comparison cities)		Chi square with Yates correction	
	Total No.	No. of SOIV Infections (%)	Total No.	No. of SOIV Infections (%)	P value	RR (95% CI)
< 4	103	33 (32%)	62	25 (40.3%)	0.36	0.87 (0.67-1.13)
4 - 9	147	57 (38.8%)	99	68 (68.7%)	<0.001	0.61 (0.49-0.76)
10 - 18	131	61 (46.6%)	95	57 (60%)	0.06	0.8 (0.64-1.0)
19 - 49	118	21 (17.8%)	157	54 (34.4%)	0.004	0.58 (0.39-0.85)
50 - 64	30	9 (30%)	27	3 (11.1%)	0.11	NA
≥ 65	7	0 (0%)	6	1 (16.7%)	1.0	NA
Total	536	181 (33.8%)	446	208 (46.6%)	<0.001	0.78 (0.69-0.88)

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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.

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 **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



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 **Production of A/Perth/16/2009 H3N2 Seed**

9 H3N2 Strains from CDC:

5 Seed Candidates Made: A/Perth/16/2009, A/Victoria/210/2009, A/Hawaii//2009, A/Quebec/RV1069/2009, A/HK/26560/2009

H3N2 Seed:

 A/Perth/16/2009

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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!

