Vaccinating Against the Pandemic H1N1 Influenza Virus

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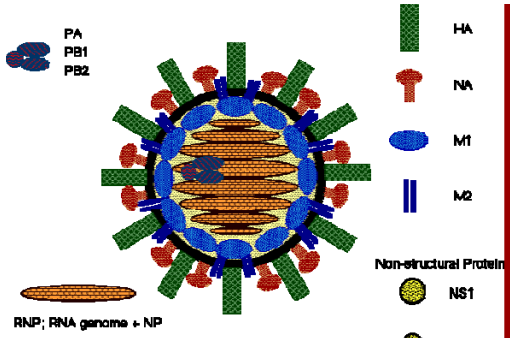
Background

Milestones in Influenza Vaccine Development

- Isolation of the influenza virus – 1933
- Research on a flu vaccine for the military in early 1940's
- Approval of first inactivated flu vaccines for commercial use in U.S. in 1945



Increased Safety, Less Reactogenicity

- Whole virus inactivated vaccines widely used until 1970s – gradually supplanted by sub-virion vaccines

Louis Pasteur

Attenuating The Flu Virus

- Published reports of flu virus attenuation activities in the1960's and 1970's
- Cold adaptation --- consistently yielded attenuated viruses
- CAIV-T for short --- same as LAIV
- University of Michigan played vital role in this research
- MedImmune licensed an LAIV vaccine in 2003

Efficacy

- Inactivated – up to 90% when strains match
- LAIV challenge studies in adults – 85% efficacy
- LAIV efficacy in children (against culture confirmed disease) for vaccine strain A/Wuhan H3N2 was 95% in first year and efficacy against non-vaccine A/Sidney was 86% in second year (revaccination with A/Wuhan)

Vaccine Production

- Availability of embryonated hen's eggs - 1yr
- Selection of strains and testing - 4 to 8 wks
- Development of agents to measure potency – 2 to 4 wks
- Manufacture, fill, and test vaccine - 10 to 12 wks

FIGURE 1. New York City residents line up for vaccinations during a smallpox vaccination campaign — New York City, 1947

Photo/Associated Press

The Last Pandemic Threat From A Swine Influenza

- January 1976 respiratory disease outbreak at Ft. Dix – several sick soldiers, one of whom died
- March 1976, several hundred persons thought involved in person to person transmission
- August 1976 fatal respiratory illness among Legionaires at meeting in Philadelphia – took 4 days to r/o swine flu

1976 Events

- September 2, President announces vaccine for all
- October 1, first flu vaccination given
- November15th week, increased incidence of GBS reported From Minnesota
- November 22, one swine flu case confirmed in Missouri

1976 Events

- December 3, another swine flu case but associated with pig exposure
- December 14, CDC announces investigation of GBS cases
- December 16, CDC suspends vaccination program pending further investigation

1976 Timing

- First dose of vaccine given 7.5 months after the virus was identified
- By 9th month after virus identified, 150 million doses of vaccine had been produced
- By 10th month, program was ended and 45 million people had been vaccinated

GBS

- GBS – background rate is 1-2 cases per 100,000 adult population
- During 1976 swine flu vaccination campaign, a rate that was about one case per 100,000 adults above the background level was noted
- Since 1976 there has been no repeat of what occurred that year regarding GBS and influenza vaccines and the true risk if any, has been very difficult to determine by epi studies

"This Time Around"

- There is a real disease this time with a pandemic severity index (PSI) of 2 (out of a scale of 1-5) in US, about like the 1957 pandemic

2009

- Vaccine production initiated in June
- Pilot vaccine lots available for clinical trials to start in August
- Five clinical trials under auspices of the National Institute of Allergy and Infectious Diseases are underway at several research centers (see: www3.niaid.nih.gov/news/QA/vteuH1N1qa.htm)

Monitoring Safety

- Enhanced VAERS
- Vaccine Safety Data Link project

The When

- 45 million doses of Pandemic H1N1 Vaccine expected to be ready for delivery near Mid-October
- All five manufacturers licensed to make influenza vaccine in the U.S. received candidate/seed lots of the vaccine in June
- Vaccine to be made by manufacturer in formulations for which that manufacturer is currently licensed to produce vaccine

- Two separate doses will most likely be required but wait for data from the trials to be sure
- Can probably be given at the same time as seasonal flu but trial data will dictate
- Can be given at same time as or any time after PPSV

Potential Complicating Factor

- Adjuvant?
- Yes – Emergency use authorization, antigen sparing, greater safety issues
- No – enables more of a routine process (current plan)

Why Two Flu Vaccines?

- If Trivalent with H1N1 upgraded to Pandemic strain, safety issues with Pandemic H1N1 part would affect all seasonal flu vaccine – not a good idea)
- If Monovalent, safety issues would at worst result in, pulling the Pandemic H1N1 vaccine and seasonal flu vaccination can still go on)

The Who and The Why

- Persons targeted for vaccination: all persons 6 months through 24 years of age
- People who live with or care for infants younger than 6 months of age
- All pregnant women
- Health care and emergency services personnel
- Persons 25 years through 64 years of age with health conditions associated with high risks for medical complications from influenza

Mechanisms of Vaccine Distribution

- Seventy percent of vaccine will be distributed through partnerships with the following health care segments: private health plan medical providers serving the targeted populations; community nonprofit clinics and schools; hospital employee health departments; DRCs; EMS/Fire Dept Med Directors; retail pharmacy chains, etc.

- Thirty percent through PODS

Final Thoughts

- A unique experience
- Some parts of what we'll have to do have been practiced, some have not
- Use the remaining time to identify and address potential roadblocks and challenges

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