

# Planning for the Novel H1N1 Influenza Vaccination Campaign

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# Influenza Prevention

- Influenza vaccination is the primary means to prevent influenza, its transmission, and associated complications



# 2009 H1N1 Vaccine

- Basic information on H1N1 Vaccine
  - Target Groups
  - Manufacturing
  - Availability
- Vaccine Distribution
  - Allocation
  - Finance
  - Dispensing
  - Clinical Management
  - Workforce
  - Safety
  - How to Register for Vaccine
- Seasonal influenza and Pneumococcal Vaccine

# Target Groups

- Advisory Committee on Immunization Practices (ACIP) met July 29<sup>th</sup> and set priority groups.
- Phased Vaccination
- Initial Target Groups:
  - Pregnant Women
  - Household and caregiver contacts of children younger than 6 months of age
  - Healthcare and emergency services personnel
  - Persons from 6 months through 24 years of age
  - Persons aged 25 through 64 years of age who have medical conditions that are associated with a higher risk of influenza complications

# Target Groups

- Prioritization within these target groups might be necessary if initial vaccine availability is insufficient to meet demand:
  - Pregnant women
  - Household and caregiver contacts of children younger than 6 months of age
  - Healthcare and emergency services personnel with direct patient contact
  - Children 6 months of age through 4 years
  - Children 5 years of age through 18 years who have medical conditions that are associated with a higher risk of influenza complications

# Target Groups

- Once demand from initial target groups is met:
  - Provide vaccine to all adults aged 25 through 64 years of age
- Vaccination can be offered to persons 65 years of age and older once demand is being met among younger groups

# Target Groups (Continued)

Priority Group	Seasonal Vaccine Recommended	Initial Target Groups for H1N1 Vaccine
Workers in health care settings	+	+
Adults age 25-64 years with underlying medical conditions**	+	+
Pregnant women	+	+
Household contacts and caregivers for children younger than 6 months of age	+	+
Adults age 65 years and older	+	
Young adults less than 25 years of age		+
Anyone who wishes to be vaccinated	+	

# Vaccine Manufacturing

- Vaccine is being manufactured
  - Novel H1N1 vaccine is being procured by the U.S. government at no cost to us.
  - The 5 manufacturers of currently licensed seasonal influenza vaccines are in the process of making H1N1 vaccine.
  - It will be available in both the inactivated (the shot) and live, attenuated (nasal spray) forms

# Vaccine Manufacturing (Continued)

- It will be available mostly in multi-dose vials (with thimerosal)-about 50%
- With lesser amounts of single-dose syringes (thimerosal-free) and nasal spray vaccine

# Manufacturing Continued

- **New information says that one dose is enough for those 10 years and up.**
- **For those 9 years and younger 2 doses will be needed.**
- 4/5 have been licensed: Not GSK
- It is very unlikely that any of the vaccine available in the US still will contain an adjuvant, an immune booster.
- Clinical trials are being conducted to determine response, safety, number of doses required, any age exceptions.

# Clinical Trials

- Some results were recently published in the New England Journal of Medicine
- Key Points in the editorial by Dr. Kathleen Neuzil:
  - One study shows that a single dose of vaccine containing the usual 15  $\mu\text{g}$  of antigen is immunogenic in a high proportion of healthy young and middle-aged adults.

# Clinical Trials (Continued)

- Another study looked at vaccine containing an adjuvant and one or two doses of an adjuvanted influenza vaccine containing 7.5  $\mu\text{g}$  of HA (50% of the standard dose), administered on various schedules, elicited robust antibody titers.
- Don't know yet if this will also be the case for children or adults who have underlying immune suppression or high-risk conditions.

# Clinical Trials (Continued)

- From seasonal vaccine we know that the immune responses in older children, pregnant women, and immunocompetent adults with chronic conditions are roughly similar to those of healthy nonpregnant adults.
- Younger children generally have inferior responses to inactivated vaccines, as compared with healthy adults, and children under 9 years of age are recommended to receive two doses the first year that they receive influenza vaccine.

# Clinical Trials-Safety

- Both vaccines tested have generally acceptable side-effect and adverse-event profiles.
- Pain or tenderness at the injection site were the most common adverse event observed.
- The local reactions seen with the adjuvanted vaccines were moderately higher than those generally seen with nonadjuvanted vaccines.
- Any association of uncommon adverse events cannot be ascertained in studies of this size.

# Clinical Trails-Safety (Continued)

- The manufacturing process for these vaccines is identical to that used for seasonal vaccines, which have a strong record of safety.
- Additional studies are ongoing that will address the immunogenicity of live-attenuated vaccines, and additional inactivated vaccines, in various age groups and on various schedules and in combination with seasonal influenza vaccines.

# H1N1 Vaccine Availability

- Availability is dependent on multiple factors including:
  - Virus growth
  - Speed of regulatory review
  - Production capacity
  - Has been released before clinical studies are completed
- Doses are being shipped this week.

# H1N1 Vaccine Amounts

- Initial planning scenarios (national amounts)
  - Bolus of 40, 80, or 160 million doses over 4 weeks
  - Weekly amounts of 10, 20, or 30 million doses per week after the bolus period
- Likely to be about 40-50 million doses initially and then 20 million doses per week
- Not working out this way
- Amounts vary by week
- Allocations are not know for sure until the amounts are announced each day.

# Distribution

- Centralized distribution will be available from CDC/McKesson Specialties
- About 90,000 + drop sites in the nation = about 3,600 in NYS, these are called ship-to-sites
- The New York State Department of Health (NYSDOH) will control distribution in cooperation with the local health departments
  - Hybrid between central distribution, state distribution, LHD distribution

# Vaccine Purchase and Allocation

- The H1N1 vaccine will be publicly funded and controlled.
  - It is being purchased by the U.S. government.
  - It will be made available at no cost.
  - Syringes, needles, sharps containers, and alcohol swabs will also be provided at no cost.
  - Vaccine will be allocated to states based on population.

# Vaccine Dispensing

- Will need to partner with the private sector to deliver vaccine
- Possible settings for vaccination:
  - Local health department clinics
  - Schools
  - Colleges and Universities
  - Provider offices (primary care, Peds, OB/GYN, Family Medicine, Internal Medicine)
  - Community health centers
  - Pharmacies
  - Health care facilities (hospitals, outpatient settings, etc.)
  - Certain occupational settings
  - Through mass or community vaccinators

# Financing Vaccine Administration

- America's Health Insurance Plans (AHIP), New York State Insurance Department (SID) and NYSDOH urge that the administration fee be covered by all insurance plans.
- AHIP: "...public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established." -CDC website
- Will be covered by Medicare and Medicaid
- A planning assumption is that the administration fee will be covered by insurance-letter, Governor's statement
- It is not clear yet how the administration fee for those who are uninsured will be covered
- Federal funds have been awarded to states to assist with the vaccination campaign

# Clinical Management

- Planning for a number of vaccine related clinical tools:
  - Fact sheets for medical providers
  - Fact sheets for patients
  - Tool kit for medical practices
  - Tool kit for OB/GYNs-ACOG
  - Tool kit for schools
  - Q and As
- Planning for training/education
  - Vaccination
  - Handling and Storage
  - Target groups, e.g. daycare centers
  - Webinars

# Workforce Partners

- Working with medical professional societies
- Volunteers
- Students of all sorts
- Looking at liability issues-Prep Act protects vaccinators, Q and A is available on the NYSDOH website
- Looking at scope of practice issues
- Mass vaccinators

# Vaccine Safety and Effectiveness

- There will be ongoing safety and effectiveness monitoring throughout the vaccine campaign.
- Will use existing safety monitoring systems:
  - Vaccine Adverse Event Reporting System (VAERS), cosponsored by the CDC and the FDA, a passive system that collected reports on adverse events
  - Vaccine Safety Datalink (VSD), a network of managed care organizations, to test signals from VAERS
  - Also, active surveillance for Guillain Barre Syndrome (GBS) incidence will occur
- Effectiveness studies will be conducted throughout the campaign.

# How to Register to Receive H1N1 Vaccine

- All sites that wish to receive H1N1 vaccine must pre-register at: <https://hcsteamwork1.health.state.ny.us/pub/>
- Requirements for registration differ for pediatric (patients less than 19 years) and adult providers.
- Some sites such as colleges and Universities and family practice sites are both
- For All Providers:
  - Part of the registration process - sign a provider agreement that has been supplied by the Federal government, with some NYS additions
  - If you already registered must go back and sign the provider agreement
  - By signing the agreement you agree to appropriately store and handle the vaccine, to give vaccines only to the CDC targeted groups, and to report vaccine usage.

# How to Register (Continued)

- Pediatric Providers have 2 other steps if NOT already active in the New York State Immunization Information System (NYSIIS), also know as the immunization registry
  - 1. Establish a NYSDOH Health Commerce System (HCS) account
  - 2. Establish access in NYSIIS
- All medical providers can use NYSIIS

# Health Commerce System Account

- Health Commerce System (HCS) (also referred to as the Health Provider Network or the HPN) is a secure web-based system designed by the NYSDOH specifically for electronically exchanging health-related data and information between health care providers and NYSDOH.
- Note: this is the same account that physicians use to order prescription pads and update their Physician Profile; all physicians should have an account.
- Completing the on-line HCS application request form will bring the user to the H1N1 vaccine pre-registration form and the HCS application information will pre-populate appropriate fields to expedite the H1N1 vaccine pre-registration process.

# NYSIIS

- NYSIIS participation is required by NYS law for providers who immunize children less than 19 years of age.
- Participating in training establishes a NYSIIS user account.
- 47 electronic health record/billing vendors are approved to automatically upload immunization information into NYSIIS.
- The website above provides additional information on an online orientation to NYSIIS and training opportunities for new users.

# More NYSIIS

- NYSIIS provides a number of advantages for providers during this campaign
  - 1) automatically generates the federally mandated weekly vaccine usage reports,
  - 2) monitors vaccine inventory to enable prompt reordering,
  - 3) generates reminder lists and letters for the second influenza vaccine dose, if required,
  - 4) provides a legal record of the vaccination,
  - 5) enables correct ascertainment of prior influenza vaccine history if patients receive some influenza vaccine doses (seasonal and/or monovalent H1N1) at other provider sites, and
  - 6) enables NYSDOH to more closely monitor possible vaccine adverse events.

# Reporting H1N1 Vaccine Usage

- For those who are vaccinated and are 19 years of age and older, NYSDOH will be providing a variety of options to report.
  - You will only have to report the number of doses administered by age groups
  - The number of doses wasted or expired
  - Weekly
- For those who are vaccinated and are 18 years of age or younger, the vaccinations must be entered into NYSIIS
- The required reports can be generated from NYSIIS so you do not need to report!

# Receiving Vaccine

- Registering does not guarantee receipt of vaccine
- Not everyone can receive vaccine at the same time
- Vaccine will be ordered county by county

# Ordering Vaccine

- The Vaccine Call Center will take orders 5 days a week.
- The NYSDOH will place orders twice per week
- At first vaccine will be allocated based on supply.
- Later will be like the regular ordering procedure for VFC vaccine and orders will be taken on a regular basis
- First doses were ordered 9/30
- Will ship out this week
- First to receive vaccine were hospitals, local health departments, and Federally Qualified Health Centers
- First doses were LAIV only

# Uses of Seasonal Flu This Fall

- Use vaccine as soon as it is available
- Protection does seem to exist throughout the year, even when given “early”
- About 118 million doses available, revised down to 113-115 million
  - 15 million doses available by mid-August
  - 40 million by 9/1
  - More than 90% will be shipped by 11/1
  - In each will be p-free and infant-toddler formulations

# Seasonal Influenza Vaccine Supply

- CDC's message:
  - All manufacturers are on target to make the expected 113-115 million doses expected.
  - Vaccine became available early
  - There is already a significant amount of vaccine in the market
  - Vaccine continues to be shipped
  - Due to low-yielding B strain and expedited production of H1N1, seasonal vaccine delivery will be extended

# Seasonal Vaccine Supply (Continued)

- Most doses will be out by the end of November instead of the end of October
- This is still more than has even been used in any influenza season
- This is still earlier than it has gotten out in any other season
- Still time to vaccinate before usual peak in February
- Also considerable double booking
- Is there more demand?

# Pneumococcal Vaccine

- Bacterial pneumonia is the most frequent complication of influenza disease.
- It is important to immunize all who are indicated to receive pneumococcal vaccine.
- Important to cover this vaccine for all who are indicated to receive it.

# Seasonal and Novel H1N1 Influenza Vaccines

- Disease from both viruses will overlap
- Vaccination for both will overlap
- Some children (those under 9 being vaccinated for the first time) will need 4 vaccines: 2 seasonal and 2 H1N1
- Adults will need 2 vaccines: 1 seasonal and 1 H1N1
- Concerns about only one flu vaccine covered by insurance per 12 month period-being addressed
  - Not appropriate for seasonal or H1N1 vaccine

# Seasonal and Novel H1N1 Influenza Vaccines

- Can give the two injectable types at the same time
- Can give combos of injectable and nasal at the same time
- Can't give the two nasal vaccines at the same time.
- Interval between doses is 28 days. May be shorter.
- Interval between injectable seasonal and H1N1 vaccine can be any length of time.

# Planning for H1N1 This Fall

- Stay tuned for more information
- Vaccine Call Center: 1-800-KID-SHOT
- Hotline for the public: 1-800-818-1987

**Questions?**