

# 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



- 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	+	7

# Vaccine Manufacturing

- Vaccine is being developed
  - Novel H1N1 vaccine is being procured by the U.S. government.
  - The 5 manufacturers of currently licensed seasonal influenza vaccines are in the process of developing 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 may be enough for certain people.**
- For others 2 doses will be needed.
- It will be produced as a licensed vaccine
- It is not known if an adjuvant, an immune booster, will be included in some of the vaccine under an Emergency Use Authorization (EUA)
- 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.

# 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
  - Will be released before clinical studies are completed
- Planning for mid-October, probably some doses in September

# 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
- In NYS (excluding NYC) this translates to about 1.7 million doses initially and then about 700,000 per week

# Distribution

- Centralized distribution will be available from CDC/McKesson Specialties
- About 90,000 + drop sites in the nation = about 3,600 in NYS
- 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
  - Took kit for medical practices
  - Tool kit for OB/GYNs
  - 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.
- Colleges and Universities are both
- For Adult Providers:
  - Once registered and the remaining details of the vaccination campaign have been finalized, you will be contacted by the vaccine program to sign the formal provider agreement that has been supplied by the Federal government
  - 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

# Health Commerce System Account

- The 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
  - You current inventory
  - Weekly
- For those who are vaccinated and are 18 years of age or younger, the vaccinations must be entered into the NYSDOH registry
- The required reports can be generated from NYSIIS

# Receiving Vaccine

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

# 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
  - 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

- CDCs message:
  - All manufacturers are on target to make the expected 118 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

- All 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?
- NYSDOH is working on an assessment of supply in the State.

# 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 probably need 3 vaccines: 1 seasonal and 2 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't give the two nasal vaccines at the same time.

# Planning for H1N1 This Fall

- Stay tuned for more information
- Contact Information:
  - [dsb06@health.state.ny.us](mailto:dsb06@health.state.ny.us)
  - 518-473-4437

Questions?