Planning for the Novel H1N1 Influenza Vaccination Campaign

Debra Blog, MD, MPH, Director
Bureau of Immunization
New York State Department of Health

October 7, 2009
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 29th 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)**

<table>
<thead>
<tr>
<th>Priority Group</th>
<th>Seasonal Vaccine Recommended</th>
<th>Initial Target Groups for H1N1 Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workers in health care settings</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Adults age 25-64 years with underlying medical conditions**</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Household contacts and caregivers for children younger than 6 months of age</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Adults age 65 years and older</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Young adults less than 25 years of age</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Anyone who wishes to be vaccinated</td>
<td>+</td>
<td>7</td>
</tr>
</tbody>
</table>
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 μg of antigen is immunogenic in a high proportion of healthy young and middle-aged adults.
– Another study looked at vaccine containing an adjuvant and one or two doses of an adjuvanted influenza vaccine containing 7.5 μg 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 known 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 known 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?