Planning for novel influenza A H1N1 vaccine distribution and administration

National Influenza Vaccine Summit

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Strategic Current & Possible New Goals

• Vaccines – Goal #1: Establish and maintain a dynamic pre-pandemic influenza vaccine stockpile available for 20 M persons (2 doses/person) or more persons depending on vaccine mfg. capacity & results of dose-sparing adjuvant studies and prime-boost immunization studies:
  - H5N1 vaccine stockpiles

• Goal #2: Provide pandemic vaccine to all U.S. citizens within 6 months of a pandemic declaration: pandemic vaccine (600 M doses)

National Strategy for Pandemic Influenza (Nov 2005) and HHS Pandemic Influenza Plan (Nov 2005)

www.pandemicflu.gov

Courtesy Robin Robinson, PhD, Director – BARDA (ASPR/HHS)
Previous pan flu planning assumptions

• Planning centered on influenza A H5N1 virus
• Disease would begin overseas
• Focused on a Pandemic Severity Index 5 scenario (severe, 1918-like)
• Assumed the potential for significant economic and social disruption
• Pre-pandemic influenza vaccine would be available for 20M critical infrastructure and key resources workers at the onset of a pandemic

Previous pan flu planning assumptions cont.

• Priority would be placed on development and production of a pandemic influenza vaccine
• Seasonal influenza vaccine production and vaccination efforts would be curtailed
• Limited number of pan flu vaccine manufacturers
• Pandemic influenza vaccine would be available in limited quantities in ~4-5 months
• Would initially implement a government-managed public sector vaccination program (federal, state and local public health w/public clinics)
Previous pan flu planning assumptions cont.

• Goal to vaccinate all persons in the U.S. who choose to be vaccinated

HOWEVER

• Initial limited supply would necessitate prioritization of vaccine

Specific objectives in a severe influenza pandemic

• Protect individuals who
  – Are essential to the pandemic response and provide care for persons who are ill (healthcare workers)
  – Maintain essential community services
  – Are at greater risk of infection due to their job (emergency responders)
  – Maintain homeland and national security

• Protect children
Novel Influenza A H1N1

• Disease began in N. America and was detected towards end of the N. Hemisphere flu season
• Epidemiologic picture continues to emerge over the summer 2009
• Vaccination planning must move forward rapidly in the summer to prepare for a fall 2009 vaccination campaign
• Necessary to plan for range of pandemic severity scenarios (mild, moderate, severe)
• Economic/social disruption may not be extensive

Novel Influenza A H1N1 cont.

• Initial supply of H1N1 vaccine may be larger than estimates based on previous pandemic planning assumptions (for an H5N1 scenario)
• Vaccine priority groups will be evaluated and revised in the context of the current epi data
• Seasonal flu vaccine supply minimally affected by novel H1N1 vaccine development and production
Novel Influenza A H1N1 cont.

- Potential for confluence of seasonal and pandemic influenza vaccination
- More limited, targeted novel H1N1 vaccination campaign may be appropriate
- Scenario planning around implementation options is necessary

Uncertainties

- Vaccine supply: Amount and timing of availability
- Formulation (unadjuvanted, adjuvanted, combination)
- Priority groups recommended for vaccination
- Severity of illness, and timing of illness in relation to vaccine availability
- Timing of availability of H1N1 and seasonal vaccines
- Demand for an H1N1 vaccine
Challenges:
Magnitude of vaccination effort

- Potentially
  - 600 million doses
  - 2 doses per person
- Compares with
  - ~150 million doses annually for all childhood vaccination
  - ~115 million doses maximum for annual flu vaccination
- May be necessary to coordinate with 1,000s of critical infrastructure and key resources sector businesses and organizations

Challenges:
Reduced public health infrastructure

Figure 1. Budget and Staff Cuts of LHDs: 2008 and 2009
Potential delivery models

- Public health-coordinated effort
- Mixed hybrid model that blends vaccination in
  - Public health-organized clinics
  - Traditional healthcare settings
  - Occupational settings
  - Retail settings

Key issues: Preparation

- Identifying and engaging providers
  - Public, private, community

- Developing payment mechanisms for vaccination
  - Funds to augment staffing for public health vaccination clinics (contracts for LHDs, community vaccinators)
  - Administration fee for private providers
    - Insured and Medicare/Medicaid
    - Vaccines for Children
    - Underinsured or uninsured adults
Key issues: Distribution

Two options

• Manufacturers/distributors ship vaccine to states using established distribution channels
• Centralized distribution (VFC-like program)

Allocation/ordering

Issues

• Need to determine how vaccine will be allocated amongst many potential vaccinating entities
• Provider need not pre-determine
• Provider inventory capacity limited
• Ordering procedures will differ depending on distribution model
Key issues: Vaccinating

- Recording and reporting doses administered
- Respecting priority groups
- Assuring receipt of second dose
- Emergency Use Authorization (EUA) requirements, if applicable

Need for contingency planning...

- What is reasonable to expect with respect to private sector delivery
- Situation in the fall could be incompatible with private sector administration
- Approach that is not dependant on private sector must also be planned for
Overarching issues

- Coordination between programs at state level, and between state/local and federal levels
- Coordination with the private sector
- Expectation management

Some key activities

- Supplemental funding for accelerated planning and early implementation
- Vaccine Implementation Steering Committee (ASTHO, NACCHO, AIM, Preparedness Directors, CSTE, NPHIC)
- Working with provider organizations, and others
- Distribution planning
- Scenario development to guide planning
Timely identification of clinically significant adverse events

- Enhanced surveillance through Vaccine Adverse Event Reporting System (VAERS)
- Active surveillance using sequential analytic methods through Vaccine Safety Datalink sites and the Defense Medical Surveillance System
- Special studies: hospital admission/discharge data, neurologist surveys, other
  - Active case finding of incident GBS in multiple areas
  - May be done through EIP sites and/or in collaboration with American Academy of Neurology

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