

Planning for novel influenza A H1N1 vaccine distribution and administration

National Influenza Vaccine Summit

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 United States Department of Health & Human Services
Office of the Secretary
Office of the Assistant Secretary for Preparedness and Response (ASPR)

U.S. Pan Flu vaccine Strategic Current & Possible New Goals

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



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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)



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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



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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



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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 over 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



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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



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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



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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



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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



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Challenges: Reduced public health infrastructure

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

NACCHO



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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



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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



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Key issues: Distribution

Two options

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



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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



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Key issues: Vaccinating

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



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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



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Overarching issues

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



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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



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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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