

Influenza A (H1N1) 2009 monovalent vaccine – Implementation overview

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Outline

- Epidemiology overview
- ACIP recommendations
- Clinical trials and licensure
- Safety monitoring
- Vaccine logistics
- Vaccine financing

Pandemic (H1N1) 2009 influenza - Summary of key epidemiologic findings in the US*

- Distribution of cases/hospitalizations/deaths
 - Highest incidence lab confirmed infections in school age children
 - Highest hospitalization rates among 0 through 4 year olds
 - Hospitalization rates for Apr-Jul 2009 approach cumulative rates for seasonal influenza among school age children and 19 through 49 year old adults
 - Fewest cases but highest case-fatality ratio in older adults
- Distribution of cases by age group is markedly different compared to seasonal influenza
 - Higher proportion of hospitalized cases in children and young adults
 - Few cases in older adults
 - No outbreaks among elderly in long term care facilities
- 70% of hospitalized cases have an underlying medical condition that confers higher risk for complications
- Pregnancy is a higher risk condition

ACIP Recommendations: Influenza A (H1N1) 2009 monovalent vaccine use*§

- Vaccinate as many as possible in 5 initial target groups (~159 mil)
 - Pregnant women
 - Household and caregiver contacts of children younger than 6 months of age (e.g., parents, siblings, and daycare providers)
 - Health-care and emergency medical services personnel¹
 - Persons from 6 months through 24 years of age
 - Persons aged 25 through 64 years who have medical conditions associated with a higher risk of influenza complications²
- Seasonal influenza vaccine coverage in these target groups is only 20-50%

ACIP Recommendations: Influenza A (H1N1) 2009 monovalent vaccine use*[§] (2)

- *Prioritization* within these 5 target groups might be necessary if initial vaccine availability is insufficient to meet demand (~42 mil)
 - Pregnant women
 - Household and caregiver contacts of children younger than 6 months of age
 - Health-care and emergency medical services personnel with direct patient contact
 - Children from 6 months through 4 years of age
 - Children and adolescents aged 5 through 18 years who have medical conditions associated with a higher risk of influenza complications

ACIP Recommendations: Influenza A (H1N1) 2009 monovalent vaccine use*[§] (3)

Once demand is met for the 5 initial target groups include:

- All other persons ages 25 through 64 years

Followed by:

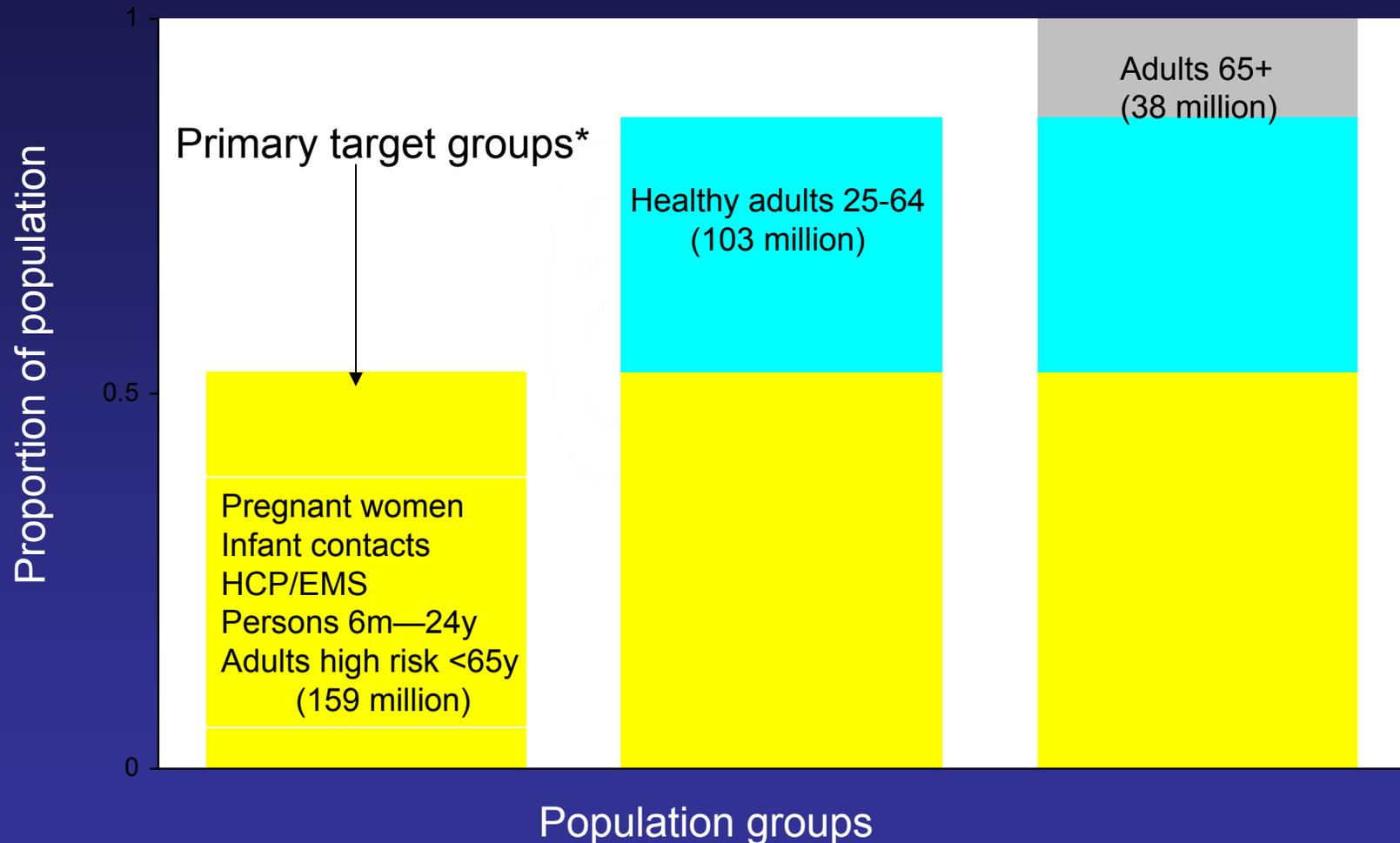
- All persons 65 years and older

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- Decisions about when to begin offering vaccination to persons outside of the initial target groups should be made in consultation with local public health authorities

Summary vaccination of population groups over time[§]

Increasing vaccine availability and demand met by immunization programs

Consult local public health authorities



[§]ACIP Influenza Workgroup Considerations. ACIP Meeting, July 29, 2009.

*Note prioritization of ~42 million persons within primary target groups if vaccine demand exceeds availability:

- 1) pregnant women; 2) contacts and care providers for infants <6 months old; 3) HCP/EMS with direct contact with patients or infectious material; 4) children aged 6m through 4 y; and, 5) children aged 5y through 18 y with chronic medical conditions

ACIP Recommendations: Influenza A (H1N1) 2009 monovalent vaccine use*§ (4)

- Vaccine should not be held in reserve for patients who already have received 1 dose but might require a second dose.
- Simultaneous administration of inactivated vaccines against seasonal influenza viruses and pandemic (H1N1) 2009 virus IS PERMISSIBLE if different anatomic sites are used.
- Simultaneous administration of live, attenuated vaccines against seasonal viruses and pandemic (H1N1) 2009 virus is NOT RECOMMENDED.
- All persons currently recommended for seasonal influenza vaccine, including those aged ≥ 65 years, should receive the seasonal vaccine as soon as it is available.

Influenza A (H1N1) 2009 monovalent vaccine – Clinical trial basic design concepts*

Licensed Manufacturers

- Monovalent vaccine
- Designed to inform dose, dosing regimen and safety
- Randomized, double-blind, controlled, dose ranging
- 2 doses (0,21d) with post-dose 1 immunogenicity assessment
- Adult and pediatric studies
- Unadjuvanted and adjuvanted arms

Influenza A (H1N1) 2009 monovalent vaccine – Licensure of unadjuvanted monovalent vaccines made by licensed process

- Manufacturers will submit a supplement to their seasonal influenza biologics license for the Influenza A (H1N1) 2009 monovalent vaccine analogous to seasonal *strain change supplement*

Influenza A (H1N1) 2009 monovalent vaccine - Safety monitoring

Objectives of the safety monitoring response:

1. Identify clinically significant adverse events following receipt of vaccine in a timely manner
2. Rapidly evaluate serious adverse events following receipt of vaccine and determine public health importance
3. Evaluate if there is a risk of Guillain-Barré syndrome (GBS) associated with receipt of vaccine
4. Communicate vaccine safety information in a clear and transparent manner to healthcare providers, public health officials, and the public

Influenza A (H1N1) 2009 monovalent vaccine - Safety monitoring (2)

Methods:

- **Vaccine Adverse Event Reporting System (VAERS)** will be the front-line monitoring system for collecting and analyzing voluntary reports of adverse events following receipt of vaccine

Influenza A (H1N1) 2009 monovalent vaccine - Safety monitoring (3)

Methods (continued):

- Vaccine Safety Datalink
 - Collaborative effort between CDC and eight large managed care organizations
- Vaccine Analytic Unit
 - Collaboration among the Department of Defense, CDC and the FDA
- Emerging Infections Programs
 - A population-based network of CDC and 10 state health departments (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN)
- American Academy of Neurologists and CDC
 - Collaboration to enhance VAERS reporting of neurological events, including GBS
- Clinical Immunization Safety Assessment (CISA)
 - Collaboration between CDC and 6 academic centers

Influenza A (H1N1) 2009 monovalent vaccine products

- Vaccines developed by five manufacturers
 - CSL, GSK, MedImmune, Novartis, Sanofi
 - Both inactivated and live intranasal vaccine
 - Thimerosal-free vaccine should be available for pregnant women and young children
 - Storage identical to seasonal vaccine
- Ancillary supplies will be provided
 - Syringes, needles, sharps containers, alcohol swabs

Influenza A (H1N1) 2009 monovalent vaccine purchase and allocation

Vaccine and Ancillary supplies

- Procured and purchased by US government and made available at no cost to providers* (defined broadly)
- Will be allocated across states proportional to population

*Primary care clinicians, hospitals, public health clinics, schools, retail clinics, workplaces, pharmacies, others

Influenza A (H1N1) 2009 monovalent vaccine planning assumptions

- Vaccine available starting mid-October
- Initial amount: At least 45 million doses will be available by Oct 15, followed by a projected average of 20M per week (up to the 195 million doses already purchased)
- Likely 2 doses required, 3-4 wks apart

Influenza A (H1N1) 2009 monovalent vaccine delivery model

Public health-coordinated effort that blends vaccination in public health-organized clinics and in the private sector (provider offices, workplaces, retail settings)



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Influenza A (H1N1) 2009 monovalent vaccine – Public health planning efforts

- Planning large scale clinics and school-located clinics
- Reaching out to providers to assess interest and capacity to provide Influenza A (H1N1) 2009 monovalent vaccine in a variety of settings

Influenza A (H1N1) 2009 monovalent vaccine providers

State/Local public health (PH) departments will designate who can serve as a vaccine provider

- Providers will enter into an agreement with state/local PH to receive vaccine
- State/Local PH will advertise registration process to potential providers
 - CDC has compiled a list of state websites and/or contacts for interested providers

Influenza A (H1N1) 2009 monovalent vaccine financing

- Providers CANNOT charge a fee for the vaccine, syringes or needles since they are being provided at no cost to the provider
- Providers may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer
- Providers are encouraged to vaccinate under- or uninsured patients; however, if unable, providers should refer these patients to a public health clinic or affiliated PH provider

Influenza A (H1N1) 2009 monovalent vaccine financing (2)

America's Health Insurance Plans (AHIP), on behalf of its members:

"Every year health plans contribute to the seasonal flu vaccination campaign in several ways:

- a) Health plans communicate directly with plan sponsors and members on the current ACIP recommendations and encourage immunization; they also provide information on where to get vaccinations, and who to contact with any questions.
- b) Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, 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"

H1N1 web resources

- http://www.cdc.gov/h1n1flu/general_info.htm
- <http://www.cdc.gov/h1n1flu/vaccination/>
- <http://www.flu.gov>

Thank you.