Influenza A (H1N1) 2009 monovalent vaccine – Implementation overview

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Outline

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

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

- Vaccinate as many as possible in 5 initial target groups (~159 mil)
  - Pregnant women (4 mil)
  - Household and caregiver contacts of children younger than 6 months of age (e.g., parents, siblings, and daycare providers) (~5 mil)
  - Health-care and emergency medical services personnel[1] (14 mil)
  - Persons from 6 months through 24 years of age (102 mil)
  - Persons aged 25 through 64 years who have medical conditions associated with a higher risk of influenza complications[2] (34 mil)
- Seasonal influenza vaccine coverage in these target groups is only 20-50%

*For unadjuvanted H1N1 vaccine

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:

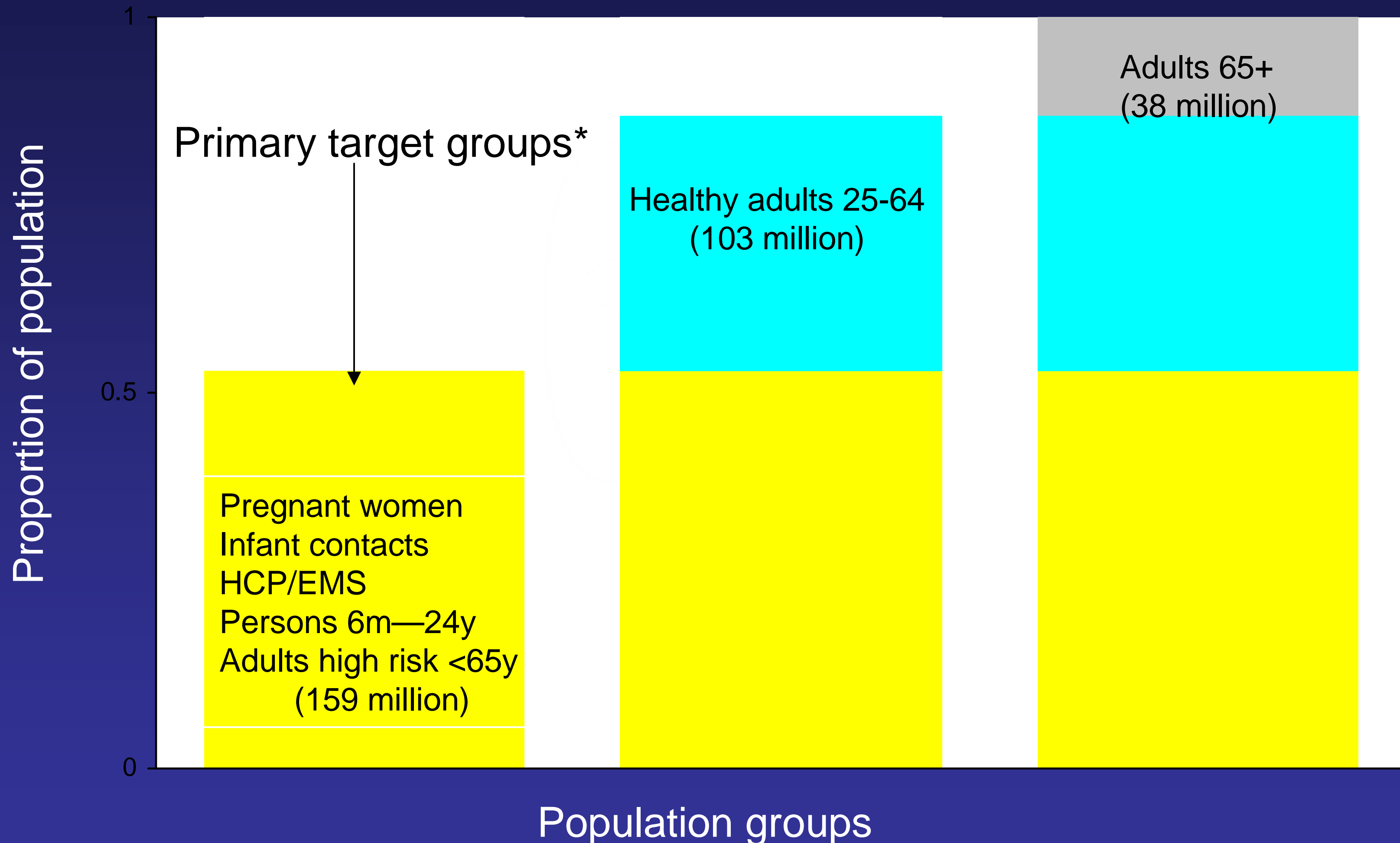
- All persons 65 years and older

- 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

Influenza A (H1N1) 2009 monovalent vaccine use

One dose vs. two doses

- Children 6 months--9 years should receive 2 doses separated by approximately 4 weeks
- Persons 10 and older should receive 1 dose

Administration with other vaccines

- Administering inactivated H1N1 vaccine at the same visit as seasonal influenza vaccine (inactivated or live, attenuated) or any other vaccines **IS PERMISSIBLE** when different anatomic sites are used
- Administering live, attenuated H1N1 influenza and live, attenuated seasonal influenza vaccines at the same visit is NOT RECOMMENDED

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

- Manufacturers submitted 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 is available for pregnant women and young children
  - Storage identical to seasonal vaccine
- Ancillary supplies will be provided
  - Syringes, needles, sharps containers, alcohol swabs, vaccination record card

*Not currently licensed

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 states and providers* (defined broadly)
- 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 supply

http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm

H1N1 Flu

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2009 H1N1 Influenza Vaccine Supply Status

October 16, 2009, 12:00 PM ET

Aggregate Totals

Posted October 16, 2009, 12:00 PM ET

Doses Allocated as of 10/14/09*	11,422,900
Doses Ordered as of 10/14/09	7,971,800
Doses Shipped as of 10/14/09**	5,885,900

*Doses allocated to project areas for ordering are those that are at the distribution depots and ready for project areas to order. Vaccine is allocated to each project area in proportion to its population (pro rata).

**There is a lag time between allocation, ordering, and shipment of doses as project areas place orders and those orders are processed and shipped.

Project areas reflect CDC Public Health Emergency Response (PHER) Grantees.

For Planners: Vaccine Allocation and Distribution Q&A

For the Public: 2009 H1N1 Influenza Vaccine Q&A, Supply and Distribution

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Atlanta, GA 30333
800-CDC-INFO
(800-232-4636)

Influenza A (H1N1) 2009 monovalent vaccine distribution

Vaccine and Ancillary supplies

- Will be sent by a central distributor to state-designated locations which will include a mix of local health departments, provider offices, workplaces, schools, hospitals, retail settings, and other sites

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

State and Local Public Health

- Planning large scale clinics including school-located clinics
- Recruiting providers 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 have developed a registration process for potential providers
  - CDC H1N1 website has a list of state websites and/or contacts for interested providers
    - http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm

H1N1 web resources

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

Footnotes

1. Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.
2. Chronic medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)

Thank you.