

2007 ACIP Recommendations for Influenza Vaccine

Anthony Fiore, MD, MPH
Influenza Division, NCIRD, CDC

National Influenza Vaccine Summit
April 19, 2007



Recommendation Changes for Influenza Vaccination: Recent Milestones

2000: All adults 50 and older

2004: All children aged 6--23 months
All contacts of children aged 0--23 months
All women who will be pregnant during influenza season

2005: All persons with any condition that can compromise respiratory function or the handling of respiratory secretions

2006: All children aged 24---59 months and their household contacts and out-of-home caregivers

220 million (73% of the population) are currently recommended for annual influenza vaccination!

Key Issues, 2007 Recommendations

- Change to vaccine composition (new H1N1 component)
- Continue to recommend against the use of adamantanes for treatment or prophylaxis
 - >30% resistance among H3N1 strains in U.S. this season
- Change in recommendations for children ages 6 months to <9 years who received a single dose during their first (previous) year of vaccination
 - **New:** recommended to receive 2 doses in second year of vaccination
- Age groups and risk groups for whom routine vaccination is recommended is not changed compared to 2006 recommendations

2007 Recommendations Box – Slide 1

Vaccination is recommended for persons, including school-age children, who want to reduce the likelihood of becoming ill with influenza or transmitting influenza to others should they become infected. Healthy, nonpregnant persons who are 5 through 49 years old can choose to receive either trivalent inactivated influenza vaccine (TIV) or live attenuated influenza vaccine (LAIV; also referred in some literature as cold-adapted influenza vaccine, trivalent [CAIV-T]). All others should receive TIV.



2007 Recommendations Box – Slide 2

All persons in the following groups should receive annual influenza vaccination. Vaccination efforts should focus on delivering vaccination to these persons if vaccine supply is limited:

- All children aged 6–59 months (i.e., 6 months to <5 years of age);
- All persons aged ≥ 50 years;
- Healthy household contacts (including children) and caregivers of infants who are younger than 6 months old
- Children and adolescents (aged 6 months–18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza virus infection;
- Women who will be pregnant during the influenza season;
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]);
- Adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration; and
- Residents of nursing homes and other chronic-care facilities.



2007 Recommendations Box – Slide 3

In addition, to prevent transmission to persons such as those identified above, all persons in the following groups should receive annual influenza vaccination with TIV or LAIV unless contraindicated:

- Health care workers;
- Healthy household contacts (including children) and caregivers of children 6-59 months of age and adults ≥ 50 years of age; and,
- Healthy household contacts (including children) and caregivers of persons with medical conditions (see above) that put them at higher risk for severe complications from influenza.

Expanding Recommendations – who is left?

- Children from 5 through 18 years old
 - ~40% in this age group already have an indication
- Adults from 19 through 49 years old
 - ~51% in this age group already have an indication
- Infants through 5 months of age
 - Burden of severe illness is high, but current vaccines unlikely to be licensed in this age group

Potential Time-Frame for Modifying Influenza Vaccination Recommendations

- **2007-2008:** Consider expanding recommendations to include all children (6 months-18 years)
 - Address scientific and implementation issues
 - Summarize results for the October 2007 ACIP meeting
- **2010-2011:** Possible expansion of recommendations to include household contacts and caregivers of school-aged children
- **2012-2013:** Possible expansion to universal vaccination (extend recommendations to persons 18-49 years)
- Each time recommendations change:
 - need to assist manufacturers, immunization programs, and public health communication experts in planning implementation

Considerations for Expanding Recommendations to Include Routine Vaccination of all School-Age Children

- Would reduce morbidity and mortality among children who are vaccinated
- Might reduce community-wide morbidity and mortality by indirect effects
- Creates expectation of immediate implementation that might not be possible
- Might exacerbate vaccine supply shortages and distribution delays if lead time for planning is insufficient

Setting the Stage: Changing the ACIP Influenza Vaccination Recommendations

- Improve surveillance
 - Safety – yearly and long term
 - Effectiveness – yearly and sustained
- Develop implementation strategies
 - School-based programs or medical home?
 - Communication messages
 - Funding
- Plan for evaluation of impact
 - Need to document to ensure sustainability
- Assess capacity
 - Vaccine manufacturing
 - Immunization delivery infrastructure



Expanding influenza vaccine recommendations to all school age children

September 2007 meeting objectives:

- Summarize current evidence
 - Burden of disease
 - Vaccine effectiveness and safety
 - Cost analyses
 - Potential direct and indirect impact
 - Experiences in pilot projects
 - Feasibility of delivering vaccine in non-medical settings
 - Manufacturing capacity
 - Parent and community opinions
- Identify current and potential
 - Implementation challenges
 - Infrastructure and resource needs
 - Priority communication messages
 - Impact assessment studies
 - Evidence gaps
- Provide report summary to ACIP (October 2007)

Future Challenges as Recommendations Expand

- Implementation of large-scale vaccination programs is difficult
 - Require flexibility in scheduling and capacity
 - 50 million school-age children each year over ~10 weeks
 - Two thirds would require an extra healthcare visit
 - Supply delays or shortages
 - Unpredictable public demand and sustainability
 - Communication messages are challenging
 - Vaccine registries not yet ready in most areas
- Vaccinating everybody ? simpler recommendations
 - Varying, changing indications for different vaccines
 - Not “one vaccine fits all”
 - Varying medical and age indications and contraindications
 - LAIV might be better at some ages, TIV at other ages
 - New vaccines (cell culture-based, adjuvanted) might be targeted to specific ages or groups

Risk- and age- based recommendations redux!

Thank You!



Routine Vaccination of 5-18 Year Olds: Efficacy and Costs

- Most studies: 50-95% (most >70%) efficacy against laboratory-confirmed influenza illness with well-matched vaccine
- Fewer studies c/w adults
 - Efficacy higher than for toddlers and infants
 - Very few adverse events
- One dose efficacy low in vaccine-naïve children <9 years old
 - Vaccine-naïve children need 2 doses*
- Multiple studies show significant reductions in influenza-like illness among vaccinated schoolchildren
 - In some studies, benefits extend to unvaccinated household members
- Routine vaccination is expected to be less cost-effective compared to current recommendations (targeting persons at higher risk of severe illness)**

*Ritzwoller *Pediatr* 2006; Allison *J Pediatr* 2006; Shuler *Pediatr* 2007

**Prosser *Emerg Infect Dis* 2006



Critical Factors That Need to be Assessed When Considering Recommendation Changes

- Safety
- Effectiveness
 - Morbidity/mortality
 - Hospitalizations
 - Outpatient and emergency department visits
- Indirect effects (preventing illness among contacts)
- Feasibility of implementation
- Cost-effectiveness
- Vaccine supply



Routine Vaccination of 19-49 Year Olds: Efficacy and Costs

- Most studies: 70-90% efficacy against laboratory confirmed influenza illness with well-matched vaccine
 - Many studies date back to several decades
- Recent study: Efficacy among 18-46 year olds against culture or PCR-confirmed influenza illness (2004-05: antigenically-drifted virus predominant)*
 - TIV efficacy 75%
 - LAIV efficacy 48%
 - Not statistically significant difference c/w TIV
 - Related mainly to reduced efficacy against influenza B
- Cost-effectiveness studies difficult to interpret
 - Season-to-season differences in influenza illness rates and vaccine effectiveness cause large variations in costs and savings
 - Most cost savings in models are derived from indirect costs such as reducing days lost from work**

*Ohmit N Engl J Med 2006

**Nichol Arch Intern Med 2001; Bridges JAMA 2000



Strain Characterization, 2006-7 Season

CDC has characterized 161 viruses through February 10

Influenza A (H1N1) [n=99]:

- 93 (94%) similar to A/New Caledonia/20/99-like viruses
- 6 (6%) with reduced titers to A/New Caledonia

Influenza A (H3N2) [n=7]

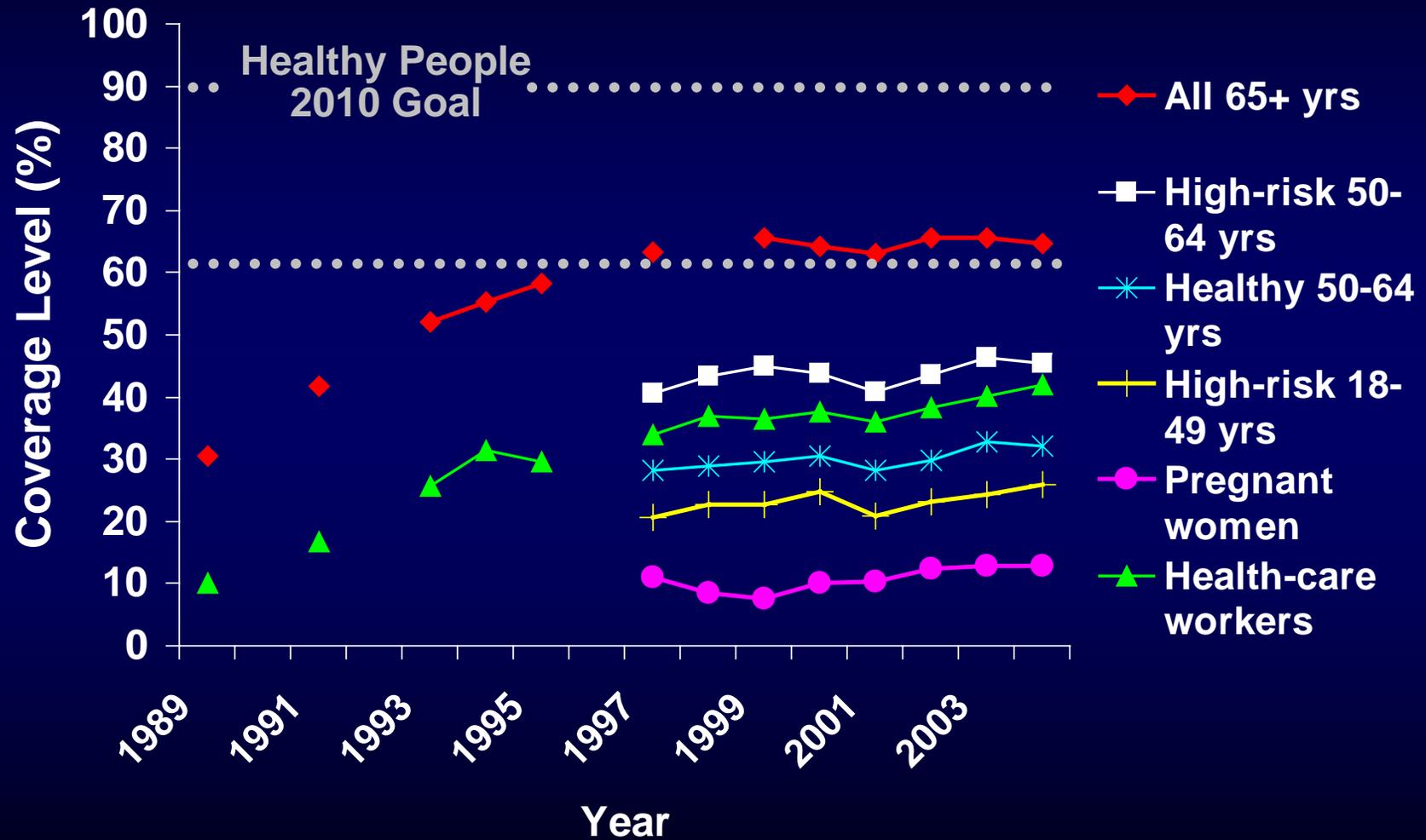
- Four similar to A/Wisconsin/67/2005-like viruses
- Three with reduced titers to A/Wisconsin/67/2005

Influenza B [n=55]

- 67% in B/Victoria lineage
 - 49% similar to B/Ohio/01/2005
 - 51% somewhat reduced titers to B/Ohio
- 33% in Yamagata lineage



Self-Reported Influenza Vaccination Coverage Levels Among Selected Adult Priority U.S. Populations, 1989-2004, National Health Interview Survey



Options to Further Reduce the Burden of Influenza

- Improve vaccination of existing target groups
 - Improve public awareness
 - Improve provider education and practices
- Establish a universal vaccination recommendation
 - Work toward universal vaccination recommendation incrementally, beginning with children
 - Strengthen adult vaccination efforts, more generally

Children ages 6 months to <9 years who received only 1 dose in their first year of vaccination: 2006 recommendations

- All children ages 6 months to <9 years being vaccinated for the first time should get two doses
 - Some only get 1 dose in the first season of being vaccinated
- 2006 recommendation: children aged 6 months to <9 years who received an influenza vaccine for the first time in the previous season but who did not receive the recommended second dose of vaccine within that first season need only receive 1 dose in the second season

Evidence supporting use of 2 doses in second year of vaccination for children ages 6 months to <9 years who received only 1 dose in their first year of vaccination

- *Englund et al, Pediatrics 2006*: When the influenza B antigen was changed for the second season, children who only received 1 dose in their first season of being vaccinated and 1 dose in second season had decreased immunologic response to the influenza B antigen compared to children who received 2 doses
- *Allison et al J Pediatr 2006*: In consecutive seasons when the influenza vaccine antigens were unchanged, effectiveness against ILI in second season was significantly less for 6-21 month old children being vaccinated for the first time who received 1 dose in both seasons compared to 6-21 month old children in their first season who received 1 dose in first season and 2 doses in second season

**Children ages 6 months to <9 years who received only 1 dose in their first year of vaccination:
2007 recommendations**

New recommendation (2007): “The ACIP now recommends 2 vaccine doses for children aged 6 months to <9 years who received an influenza vaccine for the first time in the previous season but who did not receive the recommended second dose of vaccine within that first season.”

Vaccine safety: thimerosal

“No scientifically conclusive evidence has demonstrated harm from exposure to thimerosal preservative-containing vaccine. Persons recommended to receive TIV may receive any age- and risk factor-appropriate vaccine preparation, depending on availability.”

Emphasizing Need for Better Vaccination Coverage among Health Care Workers

- “All health-care workers, as well as those in training for healthcare professions, should be vaccinated against influenza annually. Facilities that employ health-care workers should provide vaccine to workers by using approaches that maximize vaccination levels. Higher vaccination coverage levels would likely protect health-care workers, their patients, and communities; improve prevention of influenza-associated disease and patient safety; and reduce disease burden. Influenza vaccination rates among health-care workers should be regularly measured and reported.”
- Noted new JCAHO regulations that require accredited organizations to offer vaccination and measure vaccination coverage among staff
- Noted professional organization proposals, and state health law requirements, that healthcare workers be vaccinated or provide a written statement declining vaccination

Additional healthcare worker-related text suggested by reviewers

- Add sentence in summary: “All healthcare workers should be offered vaccination, and those who refuse influenza vaccination for reasons other than medical contraindications should be required to provide a signed declination.”
- Note Healthy People 2010 objective (60% coverage) for HCW immunization
- Reference additional professional society recommendations and state regulations requiring vaccination for HCWs unless they provide written declination

Recommendations for Immunization Programs

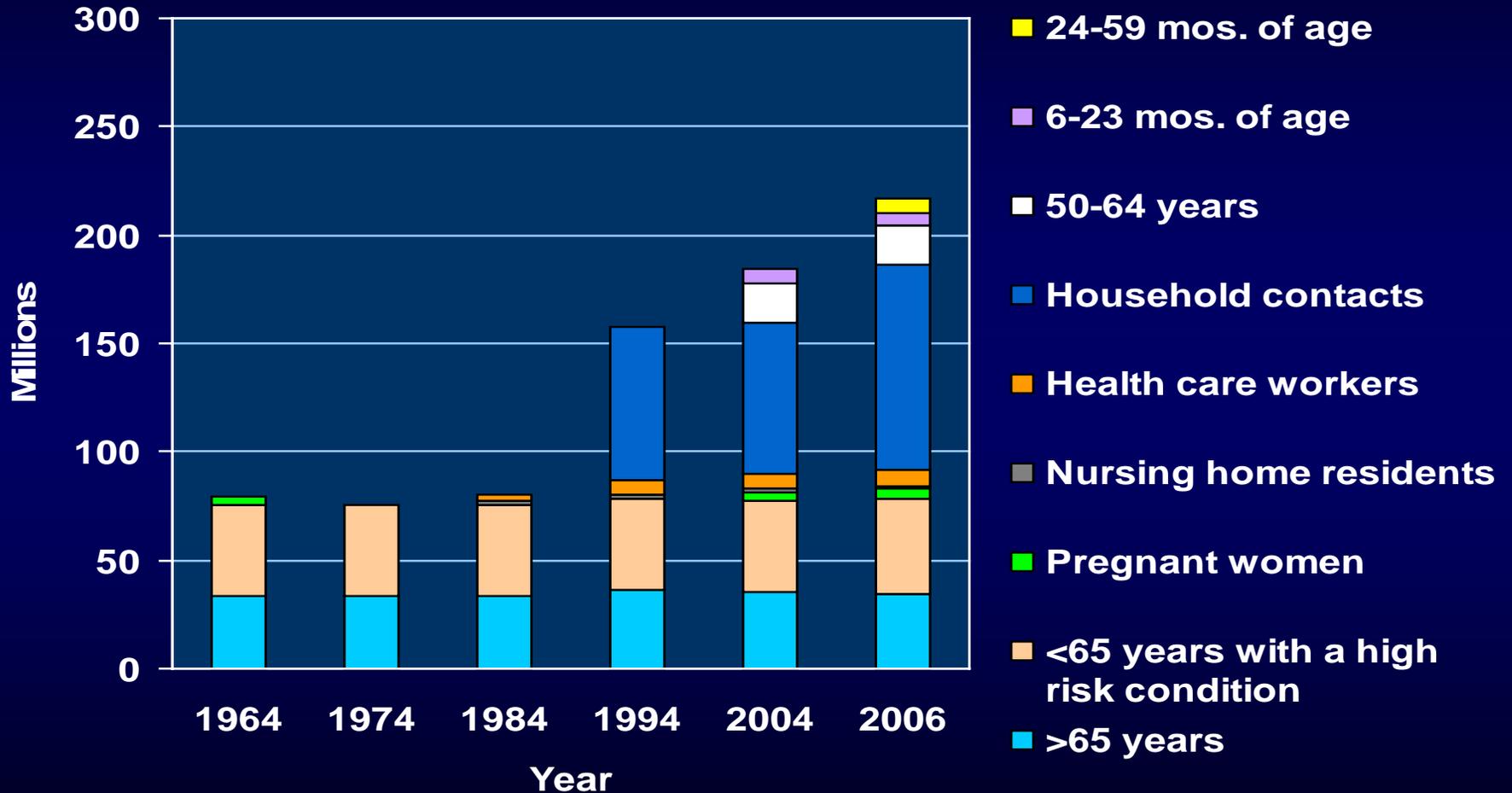
Timing of Organized Vaccination Campaigns

“Vaccination clinics should be scheduled through December, and later if feasible, with attention to settings that serve children 6-59 months of age, pregnant women, other persons aged <50 years at increased risk for influenza-related complications, persons aged ≥ 50 years, health-care workers, and household contacts of healthy children aged 24-59 months and persons at high-risk (including children aged 0–23 months) to the extent feasible. Planners are encouraged to develop the capacity and flexibility to schedule at least one vaccination clinic in December.”

Timing of vaccination

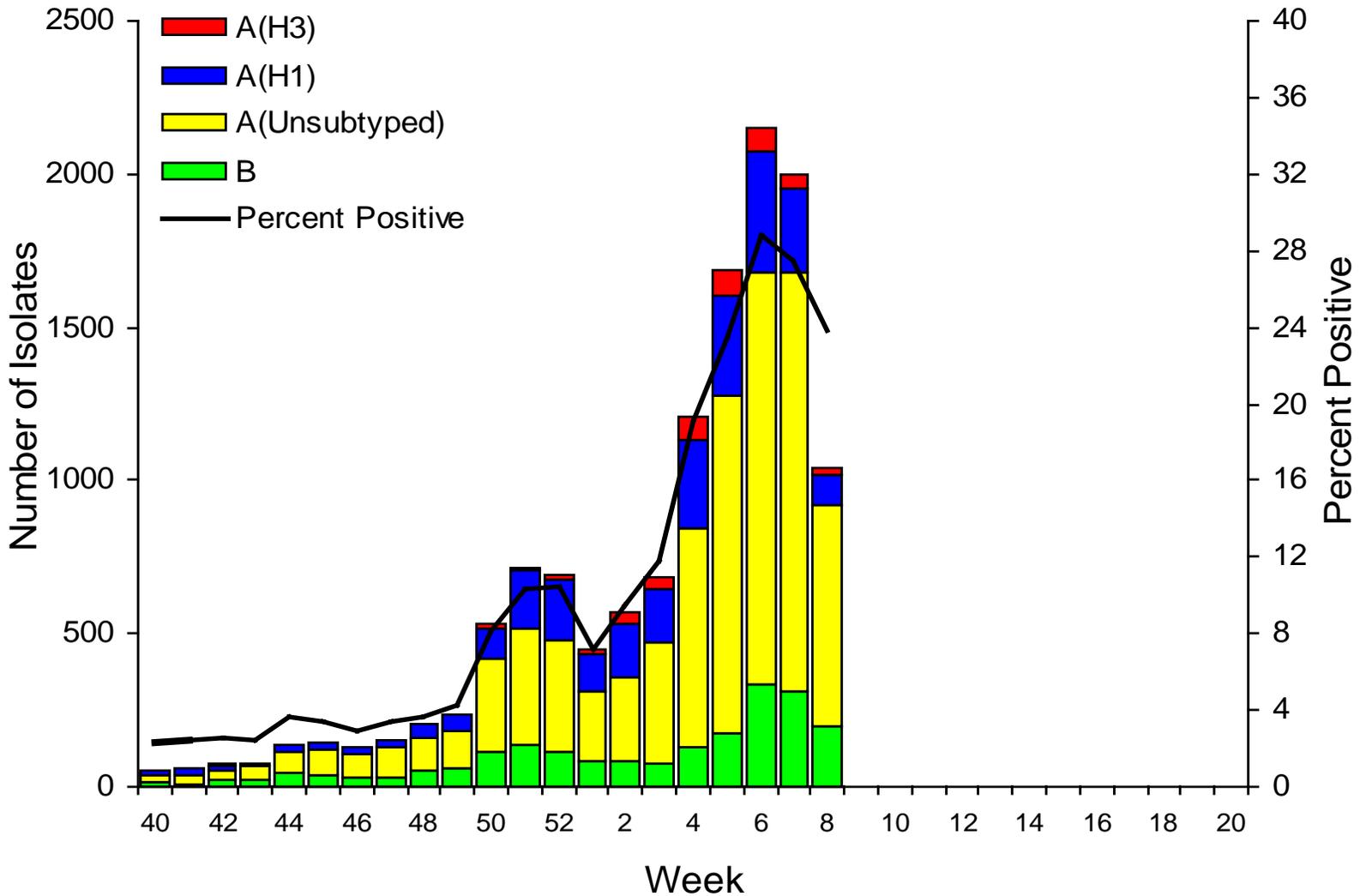
“Vaccine should be administered starting in late September and October and should continue through January and beyond because influenza activity typically peaks in February/March in the majority of seasons. Health care providers should be alert to potential vaccination opportunities during all healthcare encounters, including diagnostic or minor surgical procedures. As influenza season approaches, and whenever influenza vaccine is available, office staff should advocate or offer vaccination whenever patients contact medical care facilities, including during requests for services such as prescription refills or appointment requests.”

Estimated Size of ACIP Recommended Groups

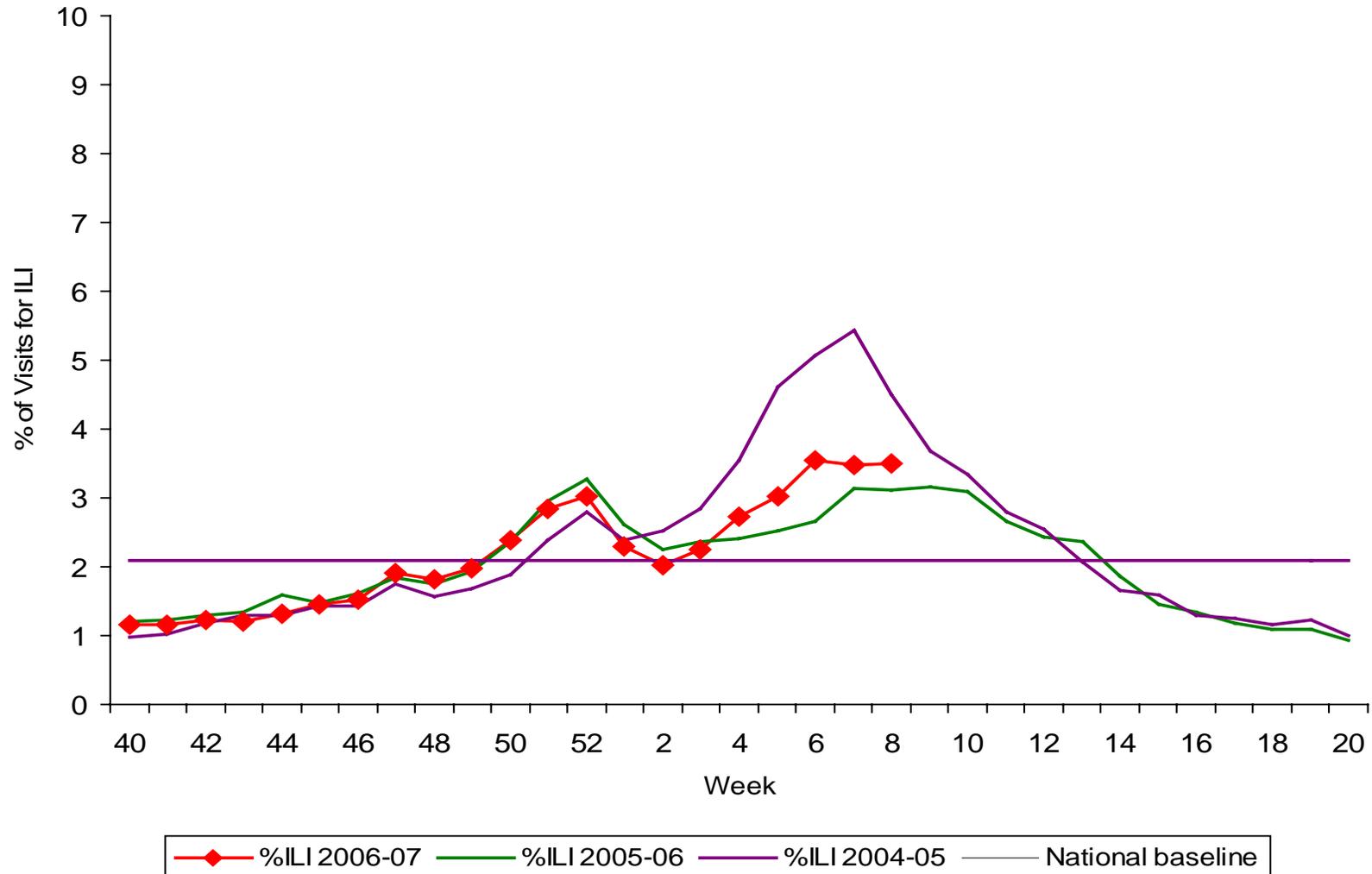


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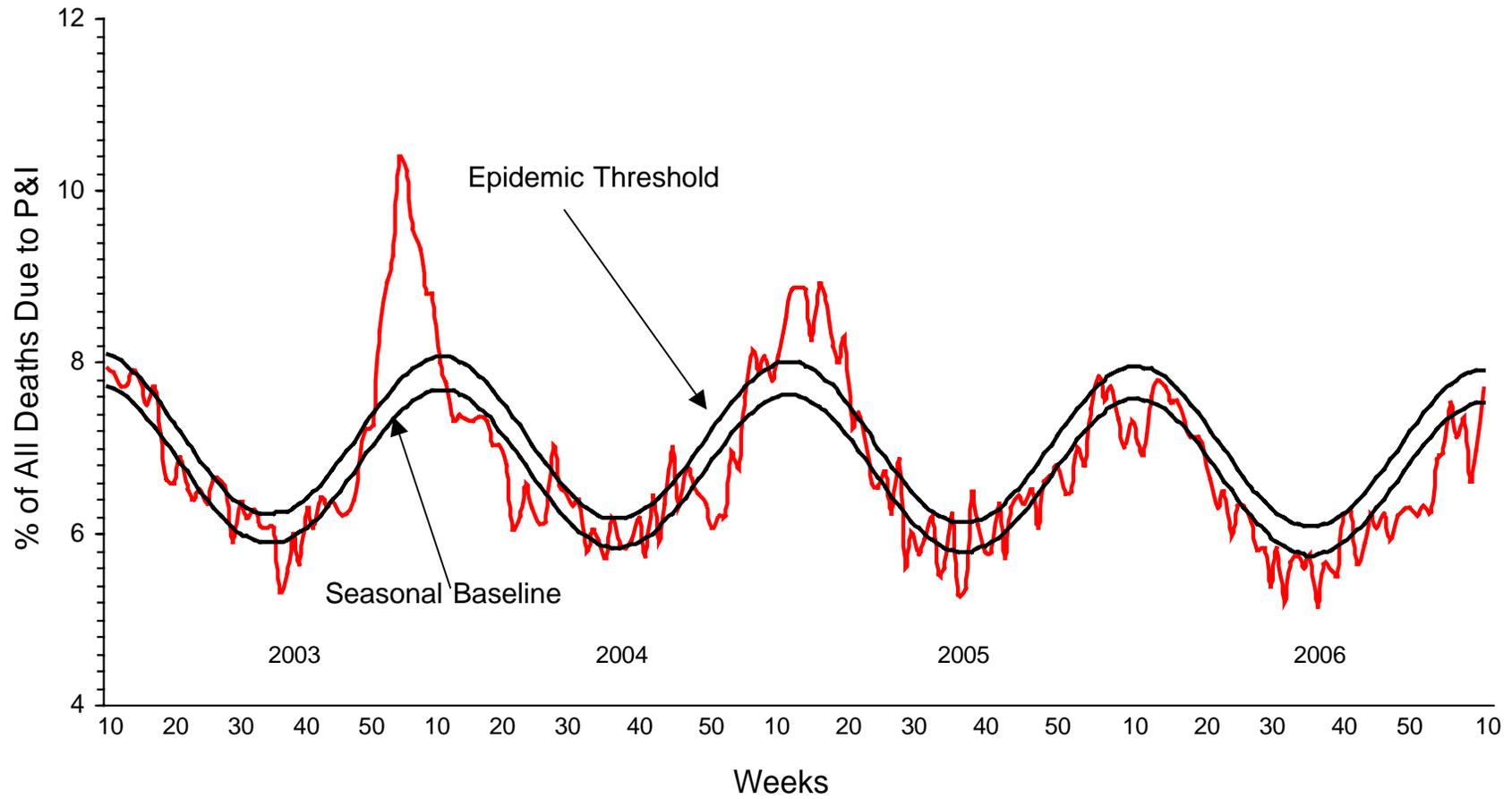
U.S. WHO/NREVSS Collaborating Laboratories Summary, 2006-07



Percentage of Visits for Influenza-like Illness Reported by Sentinel Providers, National Summary 2006-07 and Previous 2 Seasons



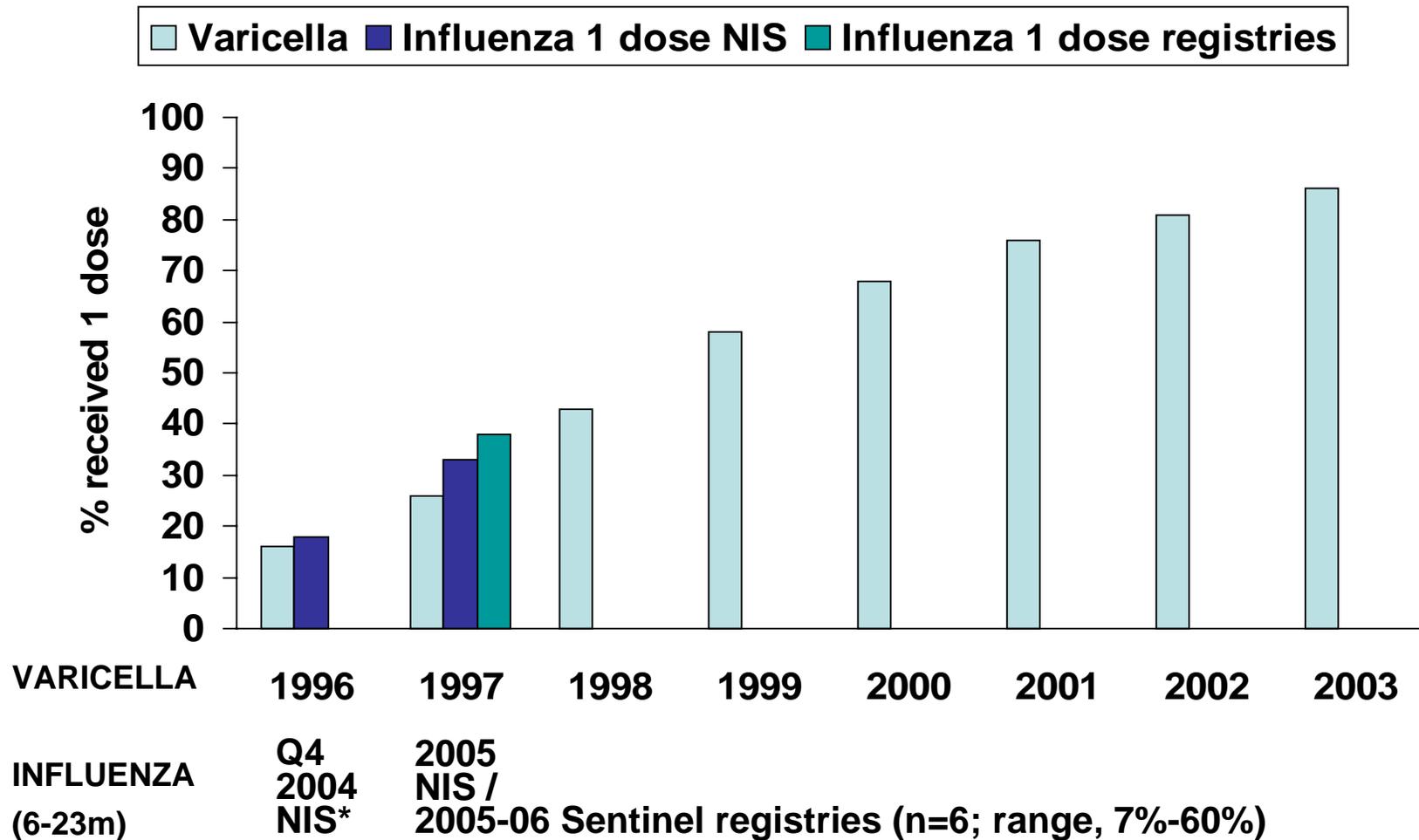
Pneumonia and Influenza Mortality for 122 U.S. Cities Week Ending 02/24/2007



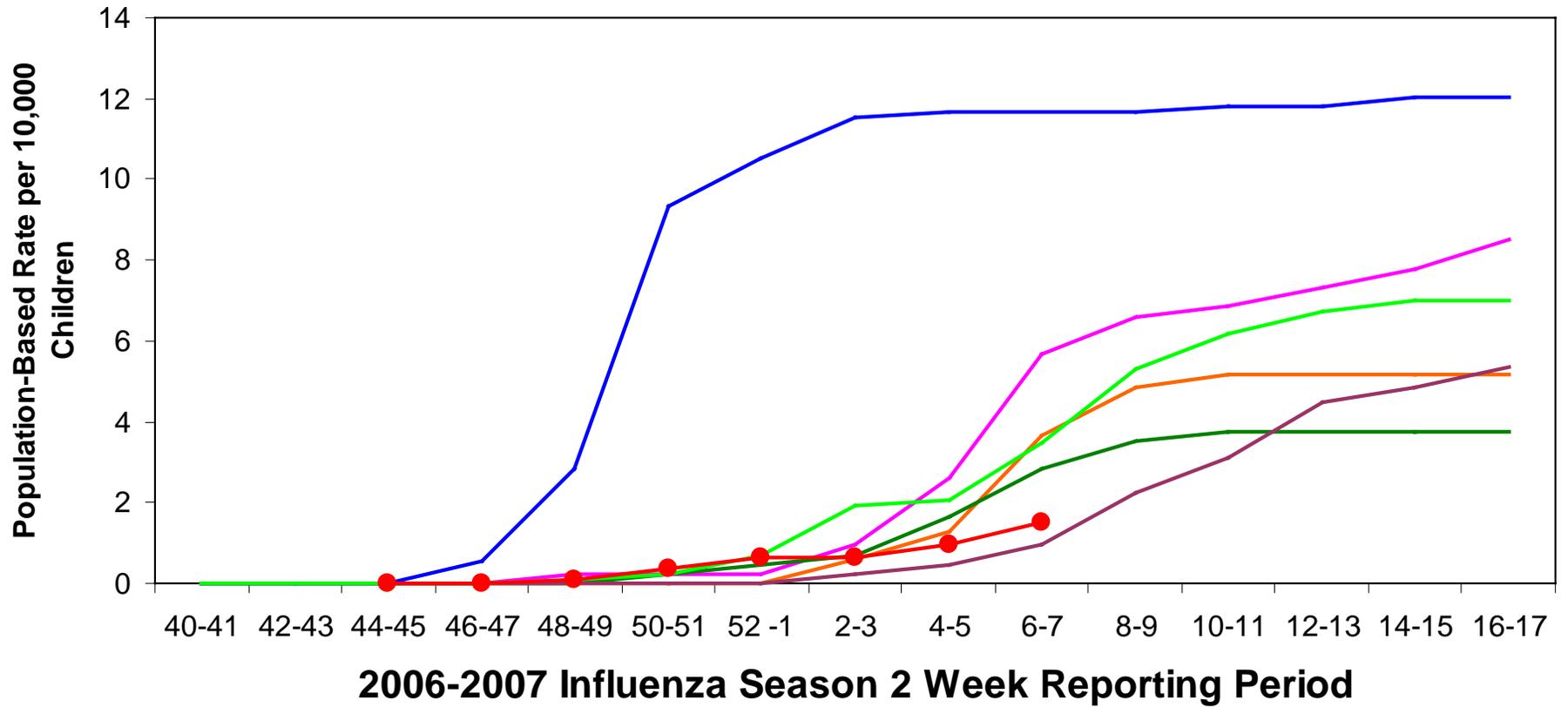
Changing the Basis for Influenza Vaccination Recommendations: A Paradigm Shift

- Previous recommendations have been designed to reduce severe complications
 - Hospitalizations
 - Mortality
- Future recommendations could incorporate
 - Indirect effects
 - Theoretical risk of reassortment

Increase in coverage for 2 newly recommended vaccines over time



NVSN Influenza Laboratory-Confirmed Cumulative Hospitalization Rates for Children 0 - 4 Years, 2006-07 and Previous 6 Seasons



Critical Factors That Need to be Assessed and Addressed As Recommendation Changes are Implemented

- Surveillance: Develop or enhance existing systems to assess influenza illness
- Vaccine Effectiveness and Safety: Monitor vaccine safety and effectiveness
- Feasibility: Assess ability to annually vaccinate school-aged children and working adults
- Vaccine Supply: Assure adequate supply exists