### Advisory Committee on Immunization Practices: Influenza Session

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#### Presentation Overview

- 2008-2009 influenza season surveillance
- Influenza vaccine coverage and effectiveness update – infants and toddlers
- Plans for monitoring antiviral resistance and vaccine effectiveness
- Adult vaccination recommendations
- Vaccination effectiveness among the elderly

## Current Vaccinations for Adults Ages 19-49

- An estimated 50% already have an indication for annual vaccination
  - Women who will be pregnant during influenza season and their contacts
  - Persons who are contacts of
    - Children younger than 5 years old
    - Adults 50 and older
    - Children and adults with chronic medical conditions that confer higher risk of influenza complications
  - Healthcare workers
- Permissive recommendation for all: "Anyone who wants to be vaccinated"

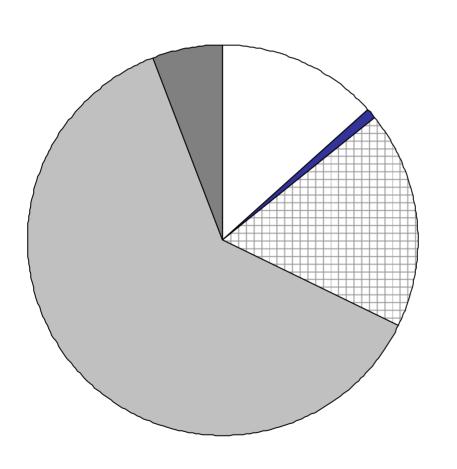
### Critical factors: Expanding annual vaccination recommendations to include <u>all</u> healthy adults ages 19-49

- Vaccine supply
- Vaccine safety
- Vaccine effectiveness
- Disease burden
- Cost-effectiveness
- Feasibility
- Acceptability
- Implementation

### Information needs that would inform decisions about adult vaccination

- Why do coverage rates among currently recommended adult groups (e.g., healthcare workers, pregnant women, contacts) remain low?
- Would more adults seek out vaccination if recommendation went from current permissive one to a universal one?
- What motivators might increase adult coverage?
- What are barriers to vaccinating in non-medical sites (e.g., workplace, retail settings)?
- What will happen with the expansion of the childhood recommendation (age 5-18), and how will we measure impact?

### U.S. population groups by vaccination recommendation status



- □ Adults 18-49 with no current annual rec
- **■** Infants <6 months
- Annual vaccine recommended (school age children)
- Annual vaccine recommended (adults)
- Annual vaccination recommended 6m--4y

### Current Discussions: Vaccination recommendations for healthy adults 19-49

- Continued support for routine vaccination of contacts of persons at risk for influenza complications, including healthy adult contacts of:
  - Persons 50 years old or older
  - Persons younger than 5 years old
  - Pregnant women
  - Persons with chronic medical conditions
- Continued support for permissive recommendation: any healthy adult who wants to be vaccinated should be vaccinated, and an ample supply of various vaccine formulations widely available (+/- preservative, nasal and injected vaccines)
- Continued support for innovative efforts to vaccinate adults in non-medical settings
  - No prescription
  - Clinics in community settings retail, pharmacies, workplace
  - Public-private partnerships

## Influenza Vaccine Effectiveness in the Elderly

## Influenza Vaccine Effectiveness in the Elderly

- Recent publications with differing estimates of effectiveness of influenza vaccination for the elderly
- Outline working group deliberations to date and future plans

#### Observational Studies of Influenza Vaccine Effectiveness

- While post-licensure observational studies are important tools for monitoring vaccine effectiveness, such studies relating to influenza vaccine in the elderly are particularly challenging to perform and interpret.
  - Confounding
    - Inadequate adjustment for medical co-morbidities can affect effectiveness estimates
    - Difficult to adjust for other characteristics of vaccinees vs non-vaccinees (vaccine seeking behavior)
  - Non-specific and limited outcome measures
    - Influenza causes a range of non-specific clinical syndromes
    - Outcomes for influenza illness in observational studies have not included laboratory-confirmation outcomes

# Recent re-analysis of randomized, controlled trial of influenza vaccine in persons 60 years and older

	Laboratory-confirmed influenza illness*				Seroprotection rate‡		
	Vaccine	Placebo	Risk ratio	Vaccine efficacy	Vaccine	Placebo	Rate ratio
	group	group	(95% CI)	(95% CI)†	group	group	(95% CI)
All ages	16/927	38/911	0·42	58%	601/909	53/899	11·2 (8·6 to
	(1·7%)	(4·2%)	(0·23 to 0·74)	(26% to 77%)	(66·1%)	(5·9%)	14·6)
60–69	12/649	29/645	0·41	59%	424/638	31/634	13·6 (9·6 to
years	(1·8%)	(4·5%)	(0·21 to 0·80)	(20% to 79%)	(66·5%)	(4·9%)	19·2)
70 years	4/278	9/266	0.43	57%	177/271	22/265	7·9
and above	(1·4%)	(3·4%)	(0.13 to 1.36)	(-36% to 87%)	(65·3%)	(8·3%)	(5·2 to 11·9)§

Data are n/N (%). \*Clinical diagnosis of influenza (made by family doctor using criteria reported elsewhere)<sup>2</sup> with at least a four-fold increase of haemagglutination inhibition titre between pre-epidemic and post-epidemic sera. †Vaccine efficacy=1-risk ratio. ‡A haemagglutination inhibition titre of at least 100 was deemed protective for influenza strain AB (A/Beijing/353/89 [H3N2]).<sup>3</sup> §Decline of rate ratio with age is significant (p=0.003; test for interaction between vaccine/placebo and age as continuous variable, logistic regression analysis, controlling for previous vaccination, age, and gender).

#### Influenza Working Group

- Recognizes that influenza causes substantial morbidity and mortality in the elderly population
- Recognizes that influenza vaccine is safe and efficacious in the elderly population
- Reaffirms the recommendation that all persons 65 years of age and over should receive influenza vaccine each year
- Reaffirms the recommendation that contacts of persons 65 year of age and over should receive influenza vaccine each year

### Influenza Working Group

- Supports prospective, population-based studies with laboratory-confirmed endpoints to monitor influenza vaccine effectiveness
- Encourages efforts to increase vaccine immunogenicity in frail elderly population
- Plans to review studies of new adjuvanted vaccines, novel delivery methods and alternative doses and schedules

#### EIP VE Study in Adults 50+

- Case-control study of TIV effectiveness in preventing influenza-confirmed hospitalizations in areas of 10 states, beginning in 2008-09 season
- Cases: hospitalized with community-acquired influenza infections as diagnosed by clinician-ordered tests
  - Chart reviews and interviews to identify vaccine status, medical conditions, and functional status indicators
- Controls: not hospitalized with influenza or respiratory infection up to the hospital admission date of corresponding case, matched by 5-year age band and county of residence
  - Potential controls identified through use of lists of households with information on ages of residents
- Plan to conduct for 3 consecutive influenza seasons
- Goal to enroll 1200 cases and 1200 controls

### Influenza Vaccine Working Group Members Kathy Neuzil, Chair

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