Vaccination of Adults in the United States

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Question One

Can patients who have had shingles get the shingles vaccine?

– 1. Yes
– 2. No
– 3. No, unless it has been at least 3 years since they had shingles
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– 2. No
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Outline of Presentation

- Burden of vaccine preventable diseases
- 2013 U.S. immunization schedule for adults and recent changes
  - Update on Tdap
  - Update on PCV13 and PPSV23
- National immunization coverage among adults
- Challenges and opportunities vaccinating adults
- Update on influenza vaccine
- Conclusions
- In 2010, ≥ 65 years accounted for 13% of US population.
- With aging of "Baby Boomers", projected population ≥65 years: 16.5% in 2020; 19.3% in 2030; and 20% in 2040.

www.Agingstats.gov
Burden of Disease Among U.S. Adults for Diseases with Vaccines Available

- **Invasive pneumococcal disease (IPD)**
  - 39,750 total cases and 4,000 total deaths in 2010
    - 86% of IPD and nearly all IPD deaths among adults

- **Influenza**
  - 3,000 to 49,000 total related deaths per year
    - ~90% among adults 65 years and older

- **Pertussis**
  - 41,880 total reported cases 2012
    - ~9,000 among adults

- **Hepatitis B**
  - 3,350 acute cases reported 2010
    - 35,000 estimated

- **Zoster**
  - about 1 million cases of zoster annually U.S.

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Potential For Substantial Reduction in Burden

- Pneumococcal vaccines
  - PPSV23 VE (vaccine effectiveness) 30-70% vs invasive pneumococcal disease (IPD)
  - PCV13 VE estimates pending
- Zoster vaccine
  - 50% VE against shingles
  - 67% VE against post-herpetic neuralgia (PHN)
- Tdap – estimate is ~70% VE (data limited for adults)
- Hepatitis B vaccine – 80-95% VE in healthy adults
- HPV vaccine – 90-100% VE against HPV vaccine types
- Influenza vaccine – varies by year and type/subtype

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm
Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedules for Persons Aged 0 Through 18 Years and Adults Aged 19 Years and Older — United States, 2013
Adult Immunizations in the U.S.

- Immunization recommendations in the United States developed through input from the Advisory Committee on Immunization Practices (ACIP)
  - ACIP is a U.S. Federal Advisory Committee – includes immunization, infectious disease, and public health experts
  - Vaccine-specific working groups and working groups for general immunizations, pediatric immunization schedule and adult immunization schedule present at publically held ACIP meetings three times per year
  - ACIP votes on recommendations to CDC
  - Final recommendations approved by the Director of CDC are published in the MMWR

- Pediatric and adult immunization schedules summarize vaccine-specific recommendations
2013 Adult Immunization Schedule

- Updated annually
- Must be interpreted along with accompanying footnotes plus the figures
- Adult schedule approved by
  - American College of Physicians
  - American Academy of Family Physicians
  - American College of Obstetricians and Gynecologists
  - American College of Nurse-Midwives
**FIGURE 1. Recommended adult immunization schedule, by vaccine and age group**

These recommendations must be read with the footnotes that follow.

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>AGE GROUP</th>
<th>19-21 years</th>
<th>22-26 years</th>
<th>27-49 years</th>
<th>50-59 years</th>
<th>60-64 years</th>
<th>≥ 65 years</th>
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<tbody>
<tr>
<td>Influenza</td>
<td></td>
<td></td>
<td></td>
<td>1 dose annually</td>
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<td>Human papillomavirus (HPV) Female*</td>
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<tr>
<td>Zoster*</td>
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<tr>
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<td>1 or more doses</td>
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<tr>
<td>Hepatitis B*</td>
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<td>3 doses</td>
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</tr>
</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; varicella vaccine recommended regardless of prior episode of zoster.

If some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication).

No recommendation

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).
<table>
<thead>
<tr>
<th>VACCINE</th>
<th>INDICATION</th>
<th>PREGNANCY</th>
<th>IMMUNE-COMPROVING CONDITIONS</th>
<th>HIV INFECTION</th>
<th>CD4+ T Lymphocyte count</th>
<th>MEN WHO HAVE SEX WITH MEN (MSM)</th>
<th>HEART DISEASE</th>
<th>CHRONIC LUNG DISEASE</th>
<th>CHRONIC ALCOHOLISM</th>
<th>CHRONIC LIVER DISEASE</th>
<th>KIDNEY FAILURE</th>
<th>END-STEM RENAL DISEASE, RECIPIENT OF HEMODIALYSIS</th>
<th>DIABETES</th>
<th>HEALTHCARE PERSONNEL</th>
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<tr>
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<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap) *</td>
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<td></td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs</td>
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<td>Human papillomavirus (HPV) Female *</td>
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<td>Human papillomavirus (HPV) Male *</td>
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<td>Hepatitis A *</td>
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</table>

* Covered by the Vaccine Injury Compensation Program

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2013. For all vaccines being recommended on the Adult Immunization Schedule, a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.html). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.
• TIV changed to IIV for inactivated influenza vaccine since QIV anticipated in 2013
• Tdap vaccination recommended during each pregnancy, preferred during weeks 27-36 of gestation.
• Documentation of provider-diagnosed disease is no longer considered acceptable evidence of immunity for measles, mumps or rubella – formerly provider diagnosis of measles or mumps was acceptable.
• HPV vaccine and pregnancy issues clarified
Clarifies who needs 1 vs 2 vs 3 doses of PPSV23 and when vaccine history unknown.

Added PCV13 vaccine information and timing of PCV13 relative to PPSV23:

- PCV13 for adults >19 years with:
  - immunocompromising conditions
  - functional or anatomic asplenia
  - CSF leaks or cochlear implants

- Give PCV13 first then PPSV23 8+ weeks later.

But, if already PPSV23 vaccinated, give PCV13 > one year after PPSV23.

Clarified that illicit injection and non-injection drug use are both indications for hepatitis A vaccine.
• Added dosing schedule information for Hepatitis B vaccine Recombivax.
- Added information on IIV vaccination among persons with only hives after exposure to eggs.
- Clarified use of antivirals when varicella or zoster vaccines given.
- Removed pregnancy as a precaution for hepatitis A vaccine so now parallel with hepatitis B and other inactivated vaccines:
  - Both vaccines remain “purple” for pregnant women – to be given only if increased risk of exposure.
U.S. IMMUNIZATION COVERAGE
Vaccination coverage for target groups by vaccine, age, and high-risk status, NHIS 2010* and 2011

Influenza, 18-64
HPV in women, 19-26
Tdap, 19-64
Hepatitis B, 19-49, HR**
Pneumococcal (ppv23), 19-64, HR


**Hepatitis B, 19-49 HR data not collected in 2011
Vaccination coverage for target groups by vaccine, age, and high-risk status, NHIS 2010* and 2011

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza, 65+</td>
<td>66.4%</td>
<td>64.9%</td>
</tr>
<tr>
<td>Pneumococcal (ppv23),65+</td>
<td>59.7%</td>
<td>62.3%</td>
</tr>
<tr>
<td>Zoster, 60+ **</td>
<td>14.4%</td>
<td>15.8%</td>
</tr>
</tbody>
</table>


** Statistically higher than 2010 coverage rates
## Race/ Ethnicity Disparity in Pneumococcal Vaccination Coverage

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>2011 Coverage %</th>
<th>% Point Difference from 2010</th>
<th>HealthyPeople 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal (ppv23) (65+)</td>
<td>62.3</td>
<td>+2.6</td>
<td>90%</td>
</tr>
<tr>
<td>-white</td>
<td>66.5</td>
<td>+3.0</td>
<td>90%</td>
</tr>
<tr>
<td>-black</td>
<td>47.6</td>
<td>+.8</td>
<td>90%</td>
</tr>
<tr>
<td>-Hispanic</td>
<td>43.1</td>
<td>+4.2</td>
<td>90%</td>
</tr>
<tr>
<td>-Asian</td>
<td>40.3</td>
<td>-7.9</td>
<td>90%</td>
</tr>
</tbody>
</table>
Conclusions

- Many missed opportunities to vaccinate adults and reduce the significant burden of disease
  - Improving coverage nationally in healthcare workers
- Racial and ethnic barriers remain
- Little progress nationally 2010 to 2011
RECOMMENDATIONS FOR PNEUMOCOCCAL VACCINES: PPSV23 AND PCV13
Question 2

PCV13 vaccine is recommended for adults in all of the following groups except:

- 1. Immune compromised persons
- 2. Persons with CSF leak or cochlear implant
- 3. Functional or anatomic asplenia
- 4. Chronic heart disease
- 5. Chronic renal disease
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- 2. Persons with CSF leak or cochlear implant
- 3. Functional or anatomic asplenia
- 4. Chronic heart disease
- 5. Chronic renal disease
Incidence of IPD in adults aged 18--64 years with selected underlying conditions, United States, 2009

- Healthy: 8 cases per 100,000 persons
- CVD: 26 cases per 100,000 persons
- Diabetes: 28 cases per 100,000 persons
- Pulmonary: 32 cases per 100,000 persons
- Kidney: 41 cases per 100,000 persons
- Liver: 52 cases per 100,000 persons
- Alcohol: 59 cases per 100,000 persons
- HIV/AIDS: 173 cases per 100,000 persons
- Hematological Cancer: 186 cases per 100,000 persons

- 20 fold increased risk
- 3-7 fold increased risk

Kyaw, JID 2005;192:377-86
ACIP and ACIP Pneumococcal Working Group

- Conducted extensive review of literature and conducted GRADE analysis

Conclusions:
- Extremely high burden of disease among immunocompromised adults
- Indirect effects of PCV13 use in children unlikely to eliminate PCV13 serotypes from immunocompromised adults
- Benefits of PCV13 use in this group outweigh the harms
- PCV13 alone may not provide adequate coverage of serotypes causing disease
- Combined regimen of PCV13 and PPSV23 likely better than either vaccine alone

Benefits likely outweigh harms and both PCV13 and PPSV23 are recommended for adults with immunocompromising conditions
ACIP-Recommended Indications for PCV13

- Adults 19 years or older with
  - Functional or anatomic asplenia
  - Immunocompromising conditions
    - Congenital or acquired immunodeficiencies
    - HIV infection
    - Chronic renal failure or nephrotic syndrome
    - Leukemias, lymphomas, Hodgkin disease
    - Generalized malignancy
    - Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids or radiation therapy
    - Solid organ transplantation
    - Multiple myeloma
  - CSF leaks and cochlear implants – PCV13 vaccine already indicated for children with these two conditions
Recommendation for PCV13 and PPSV23

- **Vaccine naïve adults:**
  - PCV13 dose is recommended to be given before PPSV23, whenever possible.
  - PPSV23 should be given at least 8 weeks after a dose of PCV13.
  - Recommendations for additional doses of PPSV23 remain unchanged.

- **PPSV23-immunized adults**
  - A dose of PCV13 is recommended to be given to adults with immunocompromising conditions who received 1 or more doses of PPSV23 1 or more years after the last PPSV23 dose.
  - Total number and interval between PPSV23 doses unchanged from current recommendations.
Question 3

How many doses of PPSV23 and PCV13 vaccine should be given to a person with HIV?

1. PPSV23 every 5 years and PCV13 once as a substitute for a dose of PPSV23
2. PCV13 once followed by one dose of PPSV23 and PPSV23 again at age 65 years?
3. PCV13 once followed by 2 doses of PPSV23 given 5 years apart?
4. PCV13 once followed by 2 doses of PPSV23 given 5 years apart and again at age 65 years
5. Neither PSV13 nor PPSV23 are recommended for persons with HIV.
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- 1. PPSV23 every 5 years and PCV13 once as a substitute for a dose of PPSV23
- 2. PCV13 once followed by one dose of PPSV23 and PPSV23 again at age 65 years?
- 3. PCV13 once followed by 2 doses of PPSV23 given 5 years apart?
- 4. PCV13 once followed by 2 doses of PPSV23 given 5 years apart and again at age 65 years
- 5. Neither PSV13 nor PPSV23 are recommended for persons with HIV.
Prevention of pneumococcal disease among adults with immunocompromising conditions

Recommendation for PPSV23-naïve adults

Adults 19 years of age or older with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23 receive a dose of PCV13 first followed by currently recommended doses of PPSV23

PCV – PPSV – PPSV + PPSV (@ 65 years or later)

≥8 weeks  >5 years
Recommendation for adults previously vaccinated with PPSV23

Adults 19 years of age or older with immunocompromising conditions, functional or anatomic asplenia, CSF leaks or cochlear implants, and who have previously received one or more doses of PPSV23 receive a dose of PCV13 one or more years after the last PPSV 23 dose was received”

For those that require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years since the most recent dose of PPSV23.
Contraindications and Precautions

- PCV13 is contraindicated for people who have had an anaphylactic reaction to a diphtheria-toxoid containing vaccine, because the antigens in PCV13 are conjugated to diphtheria CRM197 protein.

- PCV13 is contraindicated for anyone with a history of anaphylactic hypersensitivity to any vaccine component. For a list of PCV13 vaccine contents, see the package insert or http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

- PCV13 packaging does not contain latex.

- “The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines.” (ACIP General Recommendations on Immunization, p. 11)
<table>
<thead>
<tr>
<th>Risk group</th>
<th>Underlying medical condition</th>
<th>PCV13</th>
<th>PPSV23</th>
<th>PPSV23 5-year Revaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immune competent persons</strong></td>
<td>Chronic heart disease†</td>
<td>✔</td>
<td>✔</td>
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<td></td>
<td>Chronic lung disease§</td>
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<td></td>
<td>Diabetes mellitus</td>
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<td>Cerebrospinal fluid leak</td>
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<td>Cochlear implant</td>
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<td>Alcoholism</td>
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<td>Chronic liver disease, cirrhosis</td>
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<td>Cigarette smoking</td>
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<td><strong>Persons with functional or anatomic asplenia</strong></td>
<td>Sickle cell disease/other hemoglobinopathy</td>
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<td>Congenital or acquired asplenia</td>
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<td><strong>Immunocompromised persons</strong></td>
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<td>Solid organ transplant</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>Multiple myeloma</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
Question 4

Which vaccines are recommended specifically DURING pregnancy?

- 1. MMR
- 2. Hepatitis B
- 3. Tdap
- 4. Inactivated influenza vaccine
- 5. 3 and 4
- 6. None of the above
Question 4

Which vaccines are recommended specifically DURING pregnancy?

- 1. MMR
- 2. Hepatitis B
- 3. Tdap
- 4. Inactivated influenza vaccine
- 5. 3 and 4
- 6. None of the above
TDAP VACCINE RECOMMENDATION FOR PREGNANT WOMEN
Overview

- Epidemiology of pertussis in infants

- Rationale for Tdap vaccination at each pregnancy
  - Barriers to vaccinating pregnant women
  - Antibody response during pregnancy
  - Safety of multiple doses of Tdap
  - Statistics on births in the United States

- 2012 Tdap recommendation for pregnant women
Reported pertussis incidence by age group: 1990-2012*

*2012 data are provisional.

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System
Pertussis incidence among infants, 2001-2011

Shifting the timing of mother’s Tdap dose

- Provides earlier protection to mother and therefore indirect protection to infant
- High levels of transplacental maternal antibodies transferred to infants may provide direct protection
ACIP Tdap recommendation for pregnant women
2011

ACIP recommends that women’s health-care personnel implement a Tdap vaccination program for pregnant women who previously have not received Tdap. Health-care personnel should administer Tdap during pregnancy, preferably during the third or late second trimester (after 20 weeks’ gestation). If not administered during pregnancy, Tdap should be administered immediately postpartum.

CDC. Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) in Pregnant Women and Persons Who Have or Anticipate Having Close Contact with an Infant Aged <12 Months --- Advisory Committee on Immunization Practices (ACIP), 2011. MMWR; 60(41);1424-1426
Barriers to vaccinating pregnant women with Tdap

- Lack of Tdap vaccination documentation
  - Provider hesitancy to vaccinate

- Programs still focused on postpartum Tdap

- Getting the message out
  - Several initiatives aimed at improving vaccination of pregnant women

- Provider recommendation is the best predictor of vaccination (Tong 2008, Meharry 2012)


Persistence of pertussis antibodies 3 years after Tdap vaccination of non-pregnant adults

Decline of maternal antibody concentrations after receipt of Tdap

- **105 maternal delivery: placental cord pairs**
  - Mean time from Tdap vaccine: 13.7mths (2.3-23.9)
  - ~70% Tdap postpartum after prior baby
  - 19 immunized during pregnancy
  - Median gestation: 6 weeks (1 – 28 weeks)

- **Results**
  - Efficient placental transport of pertussis-specific antibodies
  - Little difference in pertussis-specific IgG in neonates of women vaccinated before or early in pregnancy
  - At time of first DTaP (2 mths), estimated PT-specific IgG in infants fell to levels likely too low to ensure protection in mothers immunized preconception.

Tdap protection for subsequent pregnancies: ACIP conclusions

- A single dose of Tdap at one pregnancy is insufficient to provide protection for subsequent pregnancies.
Percent of reported solicited adverse events in the 14 days after immunization with Tdap

Reported adverse events
Receipt of Tdap or Tdap-IPV <2 yrs after Td

- **Most commonly reported at injection site (3 to 14 days)**
  - Pain (67.9% – 82.6%)
  - Redness (20.2% – 25.2%)
  - Swelling (19.4% – 37.8%)

- **Systemic adverse events:**
  - Headache (20.2%)
  - Fever (1.7%-9.6%)
  - Myalgia (15.3%)

- **Serious adverse events related to the receipt of Tdap or Tdap-IPV - not reported or observed**


Talbot EA, et. al. The safety of immunizing with tetanus-diphtheria-acellular pertussis vaccine (Tdap) less than 2 years following previous tetanus vaccination: Experience during a mass vaccination campaign of healthcare personnel during a respiratory illness outbreak. Vaccine (2010).
Plans for safety monitoring in pregnant women vaccinated with Tdap

- **Vaccine Adverse Event Reporting System (VAERS)**
  - Enhanced monitoring for adverse events in pregnant women following Tdap
  - Inherent limitations of passive surveillance, including biased reporting

- **Vaccine Safety Datalink (VSD)**
  - Implementing studies assessing acute adverse events, adverse pregnancy outcomes affecting the mother and birth outcomes (excluding congenital anomalies) following receipt of Tdap (and other vaccines) during pregnancy.
    - Study power for Tdap depends on uptake and may take a few years
ACIP Tdap recommendation for pregnant women

2012

- ACIP recommends that providers of prenatal care implement a Tdap immunization program for all pregnant women. Health-care personnel should administer a dose of Tdap during each pregnancy, irrespective of the patient’s prior history of receiving Tdap.

- Guidance for Use
  - To maximize the maternal antibody response and passive antibody transfer to the infant, optimal timing for Tdap administration is between 27 and 36 weeks gestation although Tdap may be given at any time during pregnancy.
  - For women not previously vaccinated with Tdap, if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum.

CDC. Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women — Advisory Committee on Immunization Practices (ACIP), 2012. MMWR; 62(7);131-135
ACIP Tdap recommendation for pregnant women
Special Situations (1)

- **Pregnant women due for tetanus booster.** If a tetanus and diphtheria booster vaccination is indicated during pregnancy (i.e., >10 years since previous Td), then Tdap should be administered. Optimal timing is between 27 and 36 weeks gestation to maximize the maternal antibody response and passive antibody transfer to the infant.

- **Wound management for pregnant women.** As part of standard wound management to prevent tetanus, a tetanus toxoid–containing vaccine might be recommended for wound management in a pregnant woman if ≥5 years have elapsed since the previous Td booster. If a Td booster is recommended for a pregnant woman, health-care providers should administer Tdap.

CDC. Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women — Advisory Committee on Immunization Practices (ACIP), 2012. MMWR; 62(7);131-135
ACIP Tdap recommendation for pregnant women
Special Situations (2)

- Pregnant women with unknown or incomplete tetanus vaccination. To ensure protection against maternal and neonatal tetanus, pregnant women who never have been vaccinated against tetanus should receive three vaccinations containing tetanus and reduced diphtheria toxoids. The recommended schedule is 0, 4 weeks, and 6 through 12 months. Tdap should replace 1 dose of Td, preferably between 27 and 36 weeks gestation to maximize the maternal antibody response and passive antibody transfer to the infant.

CDC. Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women — Advisory Committee on Immunization Practices (ACIP), 2012. MMWR; 62(7);131-135
Question 5

Which groups of healthcare personnel should not be vaccinated with the live attenuated influenza vaccine?

- 1. Younger than 50 years
- 2. Non-pregnant women of child-bearing age
- 3. Work with immune compromised persons in outpatient setting
- 4. Pregnant women
- 5. Both 3 and 4
- 6. None of the above
Question 5

Which groups of healthcare personnel should *not* be vaccinated with the live attenuated influenza vaccine?

- 1. Younger than 50 years
- 2. Non-pregnant women of child-bearing age
- 3. Work with immune compromised persons in outpatient setting
- 4. Pregnant women
- 5. Both 3 and 4
- 6. None of the above
UPDATE ON INFLUENZA VACCINES
Influenza Vaccines Anticipated for 2013-14

- Multiple types of influenza vaccines available:
  - Inactivated ("killed") influenza vaccine injected in muscle
    - Ages 6 months and older, differs by manufacturer
    - Mix of trivalent and quadrivalent for 2013-14
    - Traditional egg-grown and new cell culture
  - Nasal spray vaccine (LAIV): healthy individual
    - ages 2-49 years
    - HCP not working with patients in a protected environment
    - All likely quadrivalent for 2013-14
  - High-dose inactivated injectable vaccine
    - 65 years and older
  - Intradermal inactivated vaccine
    - 18-64 years old
  - Recombinant HA vaccine – new for 2013-14
    - 18-49 year old

- ACIP currently expresses no preferences—except
  - IIV rather than LAIV for those with mild egg allergy (hives only) and those caring for severely immunosuppressed (those needing protective environments).
Influenza Vaccines Composition for 2013-14

- **Trivalent vaccines**
  - A/California/7/2009-like (2009 H1N1) virus,
  - A(H3N2) virus antigenically like the cell-propagated, or cell-grown, virus A/Victoria/361/2011 (A/Texas/50/2012),
  - B/Massachusetts/2/2012-like (B/Yamagata lineage) virus.

- **Quadrivalent vaccines containing an additional influenza B virus contain a B/Brisbane/60/2008-like (B/Victoria lineage) virus**

- **Updates from 2012-13**
  - B/Yamagata virus changed from B/Wisconsin/1/2010 to B/Massachusetts/2/2012
  - A/H3N2 component update to A/Texas/50/2012
### 2012-13 Mid-season adjusted influenza vaccine effectiveness (VE) against A and B

<table>
<thead>
<tr>
<th>Influenza A and B</th>
<th>Influenza and Vaccination Status</th>
<th>Vaccine Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Influenza-Positive Cases</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No. Vaccinated /Total (%)</td>
<td>No. Vaccinated /Total (%)</td>
</tr>
<tr>
<td>All ages</td>
<td>367/1115 (32)</td>
<td>793/1582 (50)</td>
</tr>
<tr>
<td>6 mo. – 17 years</td>
<td>118/463 (26)</td>
<td>275/565 (49)</td>
</tr>
<tr>
<td>18 – 49 years</td>
<td>100/353 (28)</td>
<td>256/604 (42)</td>
</tr>
<tr>
<td>50-64 years</td>
<td>63/174 (36)</td>
<td>143/248 (58)</td>
</tr>
<tr>
<td>65+ years</td>
<td>86/125 (69)</td>
<td>119/165 (72)</td>
</tr>
</tbody>
</table>

† Vaccine effectiveness was estimated as $100\% \times (1 - \text{odds ratio} [\text{ratio of odds of being vaccinated among the cases to the odds of being vaccinated among the controls}])$ using logistic regression. Multivariate models adjusted for age, race/ethnicity, study site, days from illness onset to enrollment, and self-rated health status. For the all ages models, age was represented as categories; age in years was used in age-stratified models.
Adjusted VE (95% CI) against circulating strains by season in US Flu VE Network

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Season 2010-11</th>
<th>Season 2011-12</th>
<th>Interim Season 2012-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mo. - 2 years</td>
<td>58%</td>
<td>58%</td>
<td>64%</td>
</tr>
<tr>
<td>3-8 years</td>
<td>69%</td>
<td>58%</td>
<td>63%</td>
</tr>
<tr>
<td>9-49 years</td>
<td>51%</td>
<td>45%</td>
<td>52%</td>
</tr>
<tr>
<td>50-64 years</td>
<td>51%</td>
<td>44%</td>
<td>54%</td>
</tr>
<tr>
<td>65+ years</td>
<td>36%</td>
<td>43%</td>
<td>27%</td>
</tr>
</tbody>
</table>
Acknowledgments For Influenza Vaccine Effectiveness Study Data

- **CDC**: Mark Thompson, Alicia Fry, Swathi Thaker, Jill Ferdinands, Po-Yung Cheng, Sarah Spencer, Erin Burns, LaShondra Berman, David Shay, Joseph Bresee, Nancy Cox

- **Group Health**: Lisa Jackson, Mike Jackson

- **Marshfield**: Ed Belongia

- **Scott & White**: Manju Gaglani

- **U Michigan**: Arnold Monto, Suzanne Ohmit

- **U Pittsburgh**: Rick Zimmerman, Tricia Nowalk
2010-11 Estimates of Influenza Vaccine Effectiveness (VE)

- Two recently published estimates for 2010-11, both cohort, non-randomized studies with laboratory confirmed outcomes
  - Castilla J, et al study in Spain Vaccine 2011
    - Population: adults with high risk conditions and/or greater than 60 years old
    - Average age 51 years in unvaccinated, 71 years in vaccinated
    - Using two different methods, adjusted estimated VE: 58-59% among high risk and elderly

2010-11 Estimates of Influenza Vaccine Effectiveness (VE)

- Kissling E, et al study in 8 EU countries, PLoS ONE 2011
  - Population: all age groups
  - Adjusted VE against all influenza
    - 0-14 years: 65.7% (95% CI 15.4-86.1)
    - 15-59 years: 41.3% (95% CI -2.6-66.4)
    - 60 and older: 59.9% (95% CI 16.7-80.7)

Influenza Vaccine Effectiveness (VE)

- Monto et al. RCT found 72% vaccine effectiveness for inactivated vaccine among adults
  - Lower VE for live attenuated influenza vaccine (LAIV) in 2007-08 in adults

- RCT of LAIV in children up to 92% effective in reducing lab confirmed influenza
  - LAIV VE higher generally in young children compared to inactivated vaccine – approved for only 2-49 years without any high risk conditions or reactive airways disease

1. Monto et al., NEJM 2009.
**Influenza Vaccination & Pregnancy**

- Influenza infection associated with increased risk to pregnant women and fetuses

- Influenza vaccination of mothers during pregnancy effective in reducing influenza associated hospitalization of their infants <6 months
  - Zaman et al, 63% effective against lab confirmed influenza
  - Poehling et al, 45-48% less likely to have influenza hospitalization

- No increased incidence of adverse events among infants or their vaccinated mothers
  - No difference in risk when given during any trimester

Vaccine and Prevention of Transmission

- Monto JID, 1973 Tecumseh study
  - From 1968 pandemic, vaccination of school children reduced illness in children and adults compared to town that did not vaccinate children

- Loeb JAMA 2009
  - Recent study of Hutterite communities in Canada
  - Found 61% reduction in adult cases of influenza by vaccinating children

- Hospital-based HCP vaccination reduced nosocomial influenza
  - Salgado, et al. Infect Control Hospital Epidemiol 2004

- Four studies of benefits of health care worker vaccination in nursing homes found reductions in patient deaths with healthcare worker vaccination
  - Referenced in HCP Vaccination MMWR November 25, 2011
Cardiovascular Disease and Influenza Vaccine

- **Randomized trials of influenza vaccination**
  - **Argentina:** Patients with recent ischemic events or undergoing angioplasty randomized to influenza vaccine or no vaccination
    - Significant reduction in cardiovascular death at 1 year
    - 6% among vaccinated versus 17% among unvaccinated (p=0.0002)
  - **Thailand:** Patients recently hospitalized with acute coronary syndrome (ACS)
    - Vaccination led to significant decrease in primary endpoint (combined major cardiovascular events, including death, hospitalization from ACS, heart failure, or stroke) 9.5% versus 19.3% (p=0.004)
    - Non-significant decrease in CV death (2.3% vs. 5.5%, p=0.088)
  - **Poland:** RPCT (double-blind) “optimally treated CAD patients” n=658
    - Death outcome after 298 days: 0.63% vaccine, 0.76% placebo (NS)
    - Composite outcome ischemic event or hospitalized for MI: 6.02% vaccine, 9.96% placebo (p=0.047, HR 0.54)

References:
- Phrommintikul Euro Heart J 2011
- Gurfinkel Euro Heart J 2004
- Ciszewski Euro Heart J 2008
Influenza Vaccine Effectiveness Conclusions

- **Vaccine effectiveness**
  - Depends on strain match and patient characteristics (age, health)
  - Can vary from year to year

- **2012-13 adjusted VE against influenza A and B was 56% (47-63%)**
  - Similar to earlier unadjusted VE of 62% (51-71%) against A and B

- **Vaccination reduced the risk of outpatient medical visits:**
  - Due to influenza A(H3N2) by half (47%); consistent for ages <65
  - Due to influenza B by two-thirds (67%); consistent for all ages

- **Similar to other interim estimates from this season**
  - Canada: VE against A(H3N2) = 45% (13%-66%)
  - UK: VE against A = 49% (-2%-75%) and against B = 52% (23%-70%)
  - I-MOVE: VE against A and B = 62% (21%-82%)

- **Even modest VE can have substantial benefits in populations where the burden of disease is high**
ADULT VACCINATION BARRIERS AND OPPORTUNITIES
Barriers to Adult Immunization

- Competing social and economic demands among adults
- Competing demands for providers’ time and vaccines often not integrated into adult medical care practice
- Adult vaccine schedule is complex
  - Especially for certain occupational and medical target groups
- Fewer public health resources for adult immunization
- Limited patient awareness and demand for adult vaccinations except for influenza vaccine
- Complex payment/coverage for adult vaccines even among the insured
- Multiple sources for vaccines and vaccine documentation
Adult Vaccination Opportunities

- **317 Program**
  - Requirement to address lagging coverage among children, adolescents AND adults
  - States can order vaccines for uninsured or underinsured adults off federal contract

- **Increasing state coverage data to be come available for adults through BRFSS**
  - Influenza and pneumococcal vaccine every year
  - Questions on Tdap, zoster, and place of influenza vaccination to be rotated every 3rd year starting in 2013

- **Increased access to vaccines at work, retail locations, pharmacies**

- **Increasing ability of health departments to bill for vaccinations**
  - Especially important for providers to refer patients for vaccines they don’t stock

- **Increasing interest in adult immunizations from private and public sectors**
Under the ACA, non-grandfathered private health plans must provide coverage for a range of preventive services without cost-sharing

- those services rated as “A” (strongly recommended) and “B” (recommended) by the U.S. Preventive Services Task Force,
- vaccinations recommended by ACIP,
- services recommended under the Bright Futures guidelines developed by HRSA and the American Academy of Pediatrics for children from birth to age 21, and
- women’s preventive services recommended by HRSA based on an Institute of Medicine study committee
Adult Vaccination Opportunities

- 80% of adults with insurance coverage
- Medicare Part B includes coverage of some vaccines for adults
  - Influenza and pneumococcal vaccine
  - Hepatitis B for high risk
  - Td as part of wound care management
- Medicare Part D – covers other vaccines
  - Out of pocket costs, etc vary by Part D program
Adult Vaccination Opportunities

MOST IMPORTANTLY

Primary care providers believe immunizations are important for adults

AND

Adults are receptive to information about and getting vaccinated when recommended by their physician or other trusted healthcare provider
Influenza vaccination coverage among pregnant women by provider recommendation and offer, mid-November 2012

http://www.cdc.gov/flu/professionals/vaccination/pregnant-women.htm
RESOURCES FOR VACCINES RECOMMENDED FOR ADOLESCENTS AND ADULTS
http://vaccine.healthmap.org
Resources for Adult

http://www.preventinfluenza.org
Conclusions

- Bulk of burden from vaccine preventable disease occurs in adults
- Although vaccine effectiveness generally lower for adults than children, vaccines offer substantial benefits
- Overall coverage for adult vaccines lags substantially behind pediatric vaccine coverage
  - Multi-factorial, but includes more complex and incomplete financing for adult vaccinations
  - Racial and ethnic disparities remain for adults, but not children
- Multiple opportunities in addition to challenges
- Efforts to raise coverage in adults includes
  - Increasing awareness of vaccines among patients
  - Increasing routine assessment of patient vaccination status and either offer or refer out to another provider
  - Increasing access to vaccination in pharmacies and workplaces (adults)
  - Improving partnerships with provider groups, payers, health plans and others to incorporate immunizations into current activities
Collaborators:
- Walter W. Williams
- Peng-Jun Lu
- Stacie Greby
- Faruque Ahmed
- Jennifer L. Liang
- Tamara Pilishvili
- Craig Hales
- Erin Kennedy
- Jim Singleton
- Helen Ding

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