**Presenter Disclosure Information**  
Alfred DeMaria, Jr., M.D.

<table>
<thead>
<tr>
<th>Consultant</th>
<th>No relevant conflicts of interest to declare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant Research/Support</td>
<td>No relevant conflicts of interest to declare</td>
</tr>
<tr>
<td>Speaker’s Bureau</td>
<td>No relevant conflicts of interest to declare</td>
</tr>
<tr>
<td>Major Stockholder</td>
<td>No relevant conflicts of interest to declare</td>
</tr>
<tr>
<td>Other Financial or Material Interest</td>
<td>No relevant conflicts of interest to declare</td>
</tr>
</tbody>
</table>

- Off-label use of certain licensed vaccines may be discussed in line with evidence-based recommendations of ACIP and other authoritative sources of recommendations; this will be noted where appropriate.
Objectives

- Participants will be able to:
  - Describe evidence-based vaccine guidelines and their use
  - Explain current evidence-based recommendations for adult immunization
  - Explicate advantages of immunization on the vaccine recipient and their contacts
  - List measures to improve immunization levels
  - Describe public health initiatives
### Figure 1. Recommended Immunization Schedule for Persons Aged 0 Through 18 Years – United States, 2014

(For those who fall behind or start late, see the catch-up schedule [Figure 2].)

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 mo</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>19–23 yrs</th>
<th>2–3 yrs</th>
<th>4–6 yrs</th>
<th>7–10 yrs</th>
<th>11–12 yrs</th>
<th>13–15 yrs</th>
<th>16–18 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B (HepB)</td>
<td>1st</td>
<td></td>
<td>2nd</td>
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<tr>
<td>Rotavirus (RV) RV1 (2-dose series), RV5 (3-dose series)</td>
<td>1st</td>
<td>2nd</td>
<td></td>
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</tr>
<tr>
<td>Diphtheria, tetanus, &amp; acellular pertussis (DTaP; &lt;7 yrs)</td>
<td>1st</td>
<td>2nd</td>
<td>3rd</td>
<td></td>
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<tr>
<td>Tetanus, diphtheria, &amp; acellular pertussis (Td; ≥7 yrs)</td>
<td>5th</td>
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<tr>
<td>Haemophilus influenza type b (Hib)</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td>3rd</td>
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<tr>
<td>Pneumococcal conjugate (PCV13)</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td>3rd</td>
<td>4th</td>
<td></td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23)</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td>3rd</td>
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<tr>
<td>Inactivated poliovirus (IPV) (&lt;18 yrs)</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td>3rd</td>
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</tr>
<tr>
<td>Influenza (IV; LAIV) 2 doses for some: See footnote 8</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td>3rd</td>
<td>4th</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR)</td>
<td>1st</td>
<td></td>
<td>2nd</td>
<td>3rd</td>
<td>4th</td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Varicella (VAR)</td>
<td>1st</td>
<td></td>
<td></td>
<td>2nd</td>
<td>3rd</td>
<td></td>
<td></td>
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<tr>
<td>Hepatitis A (HepA)</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV) females only; HPV4 males and females</td>
<td>1st</td>
<td>2nd</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Meningococcal (1) (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)</td>
<td>1st</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- **Yellow**: Range of recommended ages for all children
- **Green**: Range of recommended ages for catch-up immunization
- **Purple**: Range of recommended ages for certain high-risk groups
- **Greenish Purple**: Range of recommended ages during which catch-up is encouraged and for certain high-risk groups
- **Not Routine**: Not routinely recommended

This schedule includes recommendations in effect as of January 1, 2014. Yearly doses or additional doses recommended at this age should be administered when appropriate, even when not specified in this schedule. Dates for childhood vaccines and other recommendations are available at: [Vaccines.gov](http://www.cdc.gov/vaccines). The Advisory Committee on Immunization Practices (ACIP) website (http://www.cdc.gov/vaccines/acip) and state and local health department websites should be consulted to determine local recommendations. Additional information, including presentations and non-technical summaries, is available at: [CDC Online](http://www.cdc.gov/vaccines/basics/). This schedule is approved by the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP). Further updates are available at: [Vaccines.gov](http://www.cdc.gov/vaccines/index.htm).
<table>
<thead>
<tr>
<th>Year</th>
<th>1964 (6 diseases)</th>
<th>1985 (7 diseases)</th>
<th>1995 (10 diseases)</th>
<th>2014 (16 diseases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio</td>
<td>Polio</td>
<td>Polio</td>
<td>Polio</td>
<td>Polio</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>Diphtheria</td>
<td>Diphtheria</td>
<td>Diphtheria</td>
<td>Diphtheria</td>
</tr>
<tr>
<td>Pertussis</td>
<td>Pertussis</td>
<td>Pertussis</td>
<td>Pertussis</td>
<td>Pertussis</td>
</tr>
<tr>
<td>Tetanus</td>
<td>Tetanus</td>
<td>Tetanus</td>
<td>Tetanus</td>
<td>Tetanus</td>
</tr>
<tr>
<td>Measles</td>
<td>Measles</td>
<td>Measles</td>
<td>Measles</td>
<td>Measles</td>
</tr>
<tr>
<td>Smallpox</td>
<td>Rubella</td>
<td>Rubella</td>
<td>Rubella</td>
<td>Rubella</td>
</tr>
<tr>
<td></td>
<td>Mumps</td>
<td>Mumps</td>
<td>Mumps</td>
<td>Rotavirus</td>
</tr>
<tr>
<td></td>
<td>Hib</td>
<td>Hib</td>
<td>Hib</td>
<td>HPV</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varicella</td>
<td></td>
<td></td>
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</tbody>
</table>
“Upon reviewing stakeholder concerns and scientific literature regarding the entire childhood immunization schedule, the IOM committee finds no evidence that the schedule is unsafe. The committee’s review did not reveal an evidence base suggesting that the U.S. childhood immunization schedule is linked to autoimmune diseases, asthma, hypersensitivity, seizures, child developmental disorders, learning or developmental disorders, or attention deficit or disruptive disorders.”
Figure 1. Recommended adult immunization schedule, by vaccine and age group

<table>
<thead>
<tr>
<th>VACCINE ▼</th>
<th>AGE GROUP ▼</th>
<th>19-21 years</th>
<th>22-64 years</th>
<th>25-49 years</th>
<th>50-64 years</th>
<th>60-64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza ² ³</td>
<td></td>
<td>1 dose annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 dose</td>
</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap) ³ ⁴</td>
<td></td>
<td></td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs</td>
<td></td>
<td></td>
<td></td>
<td>1 dose</td>
</tr>
<tr>
<td>Varicella ⁴ ⁵</td>
<td></td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV) Female ⁶ ⁷</td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV) Male ⁸ ⁹</td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zoster ⁶</td>
<td></td>
<td>1 dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR) ⁷ ⁸ ⁹</td>
<td></td>
<td>1 or 2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal 13-valent conjugate ¹ ² ³</td>
<td>1 dose</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal polysaccharide (PPSV23) ³ ¹ ⁰</td>
<td>1 or 2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal ¹ ² ³</td>
<td>1 or more doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A ¹ ²</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B ¹ ²</td>
<td>3 doses</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenzae type b (Hib) ¹ ²</td>
<td>1 or 3 doses</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

² 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, zoster vaccine is recommended regardless.

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.healthcare.gov/vaccinecompensation or by telephone, 800-338-2382.

To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, NW, Washington, D.C. 20005. Telephone, 202-357-6900.
Figure 3: Vaccines that might be indicated for adults based on medical and other indications.

<table>
<thead>
<tr>
<th>VACCINE ▼</th>
<th>INDICATION ▲</th>
<th>Pregnancy</th>
<th>Immunocompromising conditions (excluding human immunodeficiency virus [HIV])</th>
<th>HIV infection CD4+ T lymphocyte count</th>
<th>Men who have sex with men (MSM)</th>
<th>Kidney failure, end-stage renal disease, receipt of hemodialysis</th>
<th>Heart disease, chronic lung disease, chronic alcoholism</th>
<th>Asplenia (including elective splenectomy and persistent complement component deficiencies)</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Health care personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td></td>
<td></td>
<td>1 dose IIV annually</td>
<td>&gt; 200 cells/μL</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap)</td>
<td></td>
<td></td>
<td>1 dose Tdap each pregnancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella</td>
<td></td>
<td></td>
<td>Contraindicated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV) Female</td>
<td></td>
<td></td>
<td>3 doses through age 26 yrs</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Human papillomavirus (HPV) Male</td>
<td></td>
<td></td>
<td>3 doses through age 26 yrs</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Zoster</td>
<td></td>
<td></td>
<td>Contraindicated</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR)</td>
<td></td>
<td></td>
<td>Contraindicated</td>
<td></td>
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<tr>
<td>Pneumococcal 13-vacp conjugate (PCV13)</td>
<td></td>
<td></td>
<td>1 dose</td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23)</td>
<td></td>
<td></td>
<td>1 or 2 doses</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Meningococcal</td>
<td></td>
<td></td>
<td>1 dose/3 doses</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td></td>
<td></td>
<td>2 doses</td>
<td></td>
<td></td>
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<tr>
<td>Hepatitis B</td>
<td></td>
<td></td>
<td>3 doses</td>
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<tr>
<td>Haemophilus influenza type b (Hib)</td>
<td></td>
<td></td>
<td>1-2 doses</td>
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</table>

*Recommended by CDC.*

For all vaccines in this table, consider the local requirements and site visits. Recommended by the American Academy of Family Physicians.
Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice

The Advisory Committee on Immunization Practices (ACIP) makes recommendations for routine vaccination of adults in the United States. Standards for implementing the ACIP recommendations for adults were published by the National Vaccine Advisory Committee (NVAC) in 2003 and by the Infectious Diseases Society of America in 2009. In addition, NVAC published a report in 2012 outlining a pathway for improving adult immunization rates. While most of these documents included guidelines for immunization practice, recent changes in the practice climate for adult immunization necessitated an update of existing guidelines.
2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

Lorry G. Rubin, Myron J. Levin, Per Ljungman, E. Graham Davies, Robin Avery, Marcie Tomblyn, Athos Bousvaros, Shireesha Dhanireddy, Lillian Sung, Harry Keyserling, and Insoo Kang

1Division of Pediatric Infectious Diseases, Steven and Alexandra Cohen Children’s Medical Center of New York of the North Shore-LIJ Health System, New Hyde Park; 2Section of Pediatric Infectious Diseases, University of Colorado Denver Anschutz Medical Campus, Aurora; 3Department of Hematology, Karolinska University Hospital; 4Division of Hematology, Department of Medicine Huddinge, Karolinska Institutet, Stockholm, Sweden; 5Department of Immunology, Great Ormond Street Hospital & Institute of Child Health, London, United Kingdom; 6Division of Infectious Diseases, Johns Hopkins University School of Medicine, Baltimore, Maryland; 7Department of Blood and Marrow Transplant, H. Lee Moffitt Cancer Center and Research Institute, University of South Florida, Tampa; 8Department of Gastroenterology and Nutrition, Children’s Hospital Boston, Massachusetts; 9Department of Allergy and Infectious Diseases, University of Washington, Seattle; 10Division of Hematology-Oncology, Hospital for Sick Children, Toronto, Ontario, Canada; 11Division of Pediatric Infectious Diseases, Emory University School of Medicine, Atlanta, Georgia 12Section of Rheumatology, Department of Internal Medicine, Yale University School of Medicine, New Haven, Connecticut

An international panel of experts prepared an evidenced-based guideline for vaccination of immunocompromised adults and children. These guidelines are intended for use by primary care and subspecialty providers who care for immunocompromised patients. Evidence was often limited. Areas that warrant future investigation are highlighted.
Seasonal Influenza Impact in U.S.

- Range of 3,349-48,614 (average 23,607) influenza-related deaths
  - 2.7 times higher when H3N2 prominent
  - ~90% among 65 and older
  - ~2,400 deaths annually among 19-64 year olds
- Annual average of 220,000 hospitalizations
  - ~50% in 65 and older
- 17-50 million people infected each year
- 70 million missed work days
- 38 million missed school days
- $3-15 billion in direct and indirect costs

MMWR 2010;59:1057-62
Influenza activity in the US during the 2013–14 season began approximately 4 weeks earlier than usual for the 2nd season in a row

The first season since 2009 that influenza A H1N1 viruses predominated (88% of all viruses were influenza A and of those 90% were A H1N1)
  - But, influenza B (22% of all viruses) and to a lesser extent A H3N2 (10% of influenza A viruses) also circulated later in the season

Nearly all of the influenza viruses sent to CDC for typing were similar to vaccine strains

Moderately severe season
  - But less severe than a typical A H3N2 predominant season
  - Highest rates of influenza disease and hospitalization among the elderly, but relatively high rates of disease among younger adults
  - Hospitalization rates among those 50-64 years were significantly higher than in all years since the 2009 pandemic

Overall vaccine effectiveness 52%

Illness and hospitalization averted by vaccination
  - 7,178,318 cases (17%)
  - 3,123,563 medically attended cases
  - 90,068 hospitalizations
Pneumonia and Influenza Mortality for 122 U.S. Cities
Week Ending September 13, 2014

% of All Deaths Due to P&I

Epidemic Threshold
Seasonal Baseline

Weeks

2010 2011 2012 2013 2014
Why a Yearly Influenza Vaccination?

- Surface antigens change

- Antibody wanes over a year
  - Little evidence that protection wanes DURING the influenza season that the vaccine was received
  - One dose recommended per season (except some children)
2014-2015 Influenza Vaccine

A/California/7/2009 (H1N1)pdm09-like virus (unchanged)
A/Victoria/361/2011 (H3N2)-like virus (unchanged)
B/Massachusetts/2/2012-like virus (unchanged)

B/Brisbane/60/2008-like
(Victoria lineage, quadrivalent vaccine)
Influenza Vaccine Formulations

- Inactivated influenza vaccine, trivalent (IIV3)
- Inactivated influenza vaccine, quadrivalent (IIV4)
- Cell culture-based inactivated influenza vaccine, trivalent (ccIIV3)
- Recombinant influenza vaccine, trivalent (RIV3)
- Live attenuated influenza vaccine, quadrivalent (LAIV4)
- IIV – high dose
- IIV – intradermal
Flu Recommendations 2014 – 2015

- IIV for everyone ≥ 6 months:
  - Pregnant women
  - Those with other contraindications to LAIV

- LAIV for healthy, non-pregnant people 2 – 49 yrs
  - ACIP says if LAIV available, use in those 2-8 yrs who are healthy without contraindications or precautions.
  - If LAIV it is not immediately available, IIV should be used. Vaccination should **not** be delayed in order to procure LAIV.

- All HCP get flu vaccine ASAP

- Begin vaccinating as soon as vaccine is available

- Continue to offer influenza vaccine in December, especially to healthcare personnel and those at high risk of complications

- Continue to vaccinate throughout influenza season (October-March)

MMWR 2014; 63:691-697
Groups at Increased Risk for Influenza Infection or Complications

- Adults 50 years of age or older
- Children
- Persons with chronic illness
  - Asthma or chronic pulmonary disease, including cystic fibrosis
  - Hemodynamically significant cardiac disease
  - Immunosuppressive disorders or therapy
  - HIV infection
  - Sickle cell anemia and other hemoglobinopathies
  - Persons 6 months to 18 years receiving chronic aspirin therapy
  - Chronic metabolic diseases, including DM
  - Any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorder, neuromuscular disease) that can compromise respiratory function, handling of secretions or increase the risk of aspiration
- Residents of long-term care facilities
- Persons 6 months to 18 years receiving chronic aspirin therapy
- Morbidly obese (BMI 40 or more)
- Pregnant women
Because all four strains contained in the 2014-2015 seasonal influenza vaccines are identical to those contained in the 2013-2014 vaccines, only **1 dose** is required for any child 6 months through 8 years of age who previously received one dose of 2013-2014 seasonal influenza vaccine.

---

**Algorithm for Determining the Number of Doses for Children 6 months through 8 years, 2014-15**

---

Did the child receive at least 1 dose of 2013-14 seasonal flu vaccine?

- **Yes**
  - 1 dose

- **No/Don’t Know**

---

Did the child receive a total of 2 or more doses of seasonal flu vaccine since July 1, 2010?

- **Yes**
  - 1 dose

- **No/Don’t Know**

---

2 doses ≥ 4 weeks apart

---

MMWR 2014; 63:691-697
TIV High-Dose

- Fluzone HD manufactured by Sanofi Pasteur
- Contains 4 X amount of influenza antigen than regular Fluzone
- Approved only for persons 65 years and older
- Produced higher antibody levels; slightly higher local reactions
- Studies have demonstrated a 25% increase in protection
- No preference stated by ACIP for HD or regular influenza vaccination

MMWR 2010;59(No. 16):485-6
Effectiveness of Influenza Vaccine Given to Mothers During Pregnancy in Preventing Hospitalization for Influenza among Their Infants

<table>
<thead>
<tr>
<th>Measure</th>
<th>Subjects aged &lt;6 months</th>
<th>Subjects aged ≥6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. (%) of case infants; no. (%) of control infants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother was vaccinated</td>
<td>2 (2.2); 31 (19.9)</td>
<td>1 (4.6); 2 (5.6)</td>
</tr>
<tr>
<td>Mother was not vaccinated</td>
<td>89 (97.8); 125 (80.1)</td>
<td>21 (95.5); 34 (94.4)</td>
</tr>
<tr>
<td>Vaccine effectiveness (95% CI), %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unadjusted</td>
<td>90.7 (59.9–97.8)(^a)</td>
<td>−41.4 (−2257.3 to 91.5)(^b)</td>
</tr>
<tr>
<td>Adjusted(^c)</td>
<td>91.5 (61.7–98.1)(^a)</td>
<td>...</td>
</tr>
</tbody>
</table>

**NOTE.** CI, confidence interval.

\(^a\) \(P = .001\).

\(^b\) \(P = .809\).

\(^c\) The adjusted model for subjects aged <6 months retained vaccination of household contacts and prematurity.
Influenza Vaccination Rate Among Pregnant Women by Attitude Toward Vaccine and Infection, and Clinician Recommendation (MMWR, Sept. 19, 2014 / 63(37);816-821)

- **Recommended and Offered**
- **Recommended**
- **No Recommendation**

<table>
<thead>
<tr>
<th>Attitude</th>
<th>Recommended and Offered</th>
<th>Recommended</th>
<th>No Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive attitude toward efficacy</td>
<td>75%</td>
<td>45%</td>
<td>10%</td>
</tr>
<tr>
<td>Positive attitude toward safety</td>
<td>76%</td>
<td>46%</td>
<td>10%</td>
</tr>
<tr>
<td>Concerned about influenza</td>
<td>80%</td>
<td>55%</td>
<td>15%</td>
</tr>
</tbody>
</table>
Seasonal Influenza Vaccination Rates for Massachusetts Adults

MA BRFSS  Data collected methods changed in 2011.
Dispelling Myths

- A flu shot can cause flu
  - It can’t

- The flu shot made me sick.
  - Rare, more often coincidence

- I never get sick
  - Anyone can get flu, no special immunity

- I am healthy, I don’t have to worry about influenza
  - Anyone can have a rare complication and anyone can spread influenza to someone who is high risk

- Flu shots have many side effects
  - Adverse events occur less often than with common OTC and prescribed drugs
Side Effects of Inactivated Flu Vaccine


<table>
<thead>
<tr>
<th></th>
<th>Vaccine</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic complaint</td>
<td>34.1%</td>
<td>35.2%</td>
</tr>
<tr>
<td>Arm soreness</td>
<td>63.8%</td>
<td>24.1%</td>
</tr>
</tbody>
</table>
Why Influenza Vaccination for Healthcare Personnel?

1. High risk of exposure
2. Prevents illness
3. Keeps HCW and colleagues at work
4. Keeps patients healthier
5. Keeps HCW family healthier
6. Saves costs for HCW and the health care system
7. Provides a good example
Percentage of health-care personnel (HCP) who received influenza vaccination, by occupation type

Internet panel survey, United States
Overall Influenza Vaccine Coverage of Personnel at Massachusetts Acute Care Hospitals
There is no logical reason for a healthcare worker not to get a flu shot, except for a valid medical contraindication.
New Information About Live Attenuated Influenza Vaccine

- LAIV effectiveness concerns
  - No measurable effectiveness against influenza A H1N1 in a study of children
  - But, ACIP and CDC recommend preferential LAIV for children 2-8 years old

- No change in recommendation
  - There is substantially more circulation of influenza A (H3N2) and B viruses and very little circulating H1N1, so far
  - LAIV has been shown to offer good protection against influenza A (H3N2) and influenza B viruses
  - LAIV may offer better protection than IIV against antigenically drifted viruses (H3N2) that may circulate this season
  - Vaccine providers have received their vaccine for the 2014-2015 season and have likely administered a good proportion of it
Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, 2014-15
2014-2015 Influenza A H3N2 Antigenic Mismatch

- A/Switzerland-like H3N2 viruses were first detected in the United States in small numbers in March of 2014 and began to increase through the spring and summer
- A/Switzerland/9715293/2013 is related to, but antigenically and genetically distinguishable, from H3N2 vaccine virus
- Accounting for an increasing percentage of characterized strains

Implications

- H3N2 tends to cause more severe disease
- Decreased vaccine efficacy
- Vaccination still provides some protection, especially against complications
- LAIV may be better for children despite reduced H1N1 efficacy
Pneumococcal Polysaccharide Vaccine
(MMWR September 3, 2010 / 59(34);1102-1106)

- Adults 65 years and older
- Persons 2 years and older with
  - Chronic illness (lung disease, cardiovascular, diabetes, liver diseases (including cirrhosis), alcoholism, renal failure or nephrotic syndrome
  - Anatomic or functional asplenia (e.g., sickle cell disease) vaccinate ≥ 2 weeks before surgery
  - Immunocompromised (disease, chemotherapy, steroids)
  - HIV infection (vaccinate soon after diagnosis)
  - Residents of long term care facilities
- Persons 19-64 y.o. with asthma or who smoke cigarettes
- Routine use in American Indians/Alaska Native (AI/AN) is no longer recommended
- In special situations, public health authorities may recommend PPSV23 for some groups of AI/AN who are 50-64 years of age (and children 24-59 months of age)
## Indications for PCV13 and PPSV23 for adults ≥19 years

<table>
<thead>
<tr>
<th>Risk group</th>
<th>Underlying medical condition</th>
<th>PCV13</th>
<th>PPSV23</th>
<th>Revaccination 5 yrs after first dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent persons</td>
<td>Chronic heart disease†</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Chronic lung disease§</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Diabetes mellitus</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Cerebrospinal fluid leak</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Cochlear implant</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Alcoholism</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Chronic liver disease, cirrhosis</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Cigarette smoking</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Persons with functional or anatomic asplenia</td>
<td>Sickle cell disease/other hemoglobinopathy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Congenital or acquired asplenia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>Congenital or acquired immunodeficiency†</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Human immunodeficiency virus infection</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Chronic renal failure</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Nephrotic syndrome</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Leukemia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Lymphoma</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Hodgkin disease</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Generalized malignancy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Iatrogenic immunosuppression**</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<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>

* All adults aged ≥65 years should receive a dose of PPSV23, regardless of previous history of vaccination with pneumococcal vaccine.
† Including congestive heart failure and cardiomyopathies, excluding hypertension.
§ Including chronic obstructive pulmonary disease, emphysema, and asthma.
¶ Includes B-(humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).
** Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.
Incidence of Invasive Pneumococcal Disease among all adults, U.S., 2009

CDC, ABCs, unpublished, 2012
Incidence of Invasive Pneumococcal Disease Among Adults ≥65 Years by Serotype, 1998-2010

PCV7 introduced

PCV13 introduced

PCV7

PCV13/non-PCV7

ABCs unpublished data, continuous sites
13-valent Pneumococcal Conjugate Vaccine (PCV13) for Adults

- Licensed for use among adults ≥50 years old on 12/30/11
- FDA approved under the Accelerated Approval Pathway
- Based on non-inferior immunogenicity compared to PPSV23

Indications

- Prevention of pneumococcal disease (including pneumonia and invasive disease) in adults 50 years of age and older
- Prevention of disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F

Post-approval condition of licensure: Randomized controlled trial of PCV13 against pneumococcal pneumonia among adults ≥65 years old in the Netherlands (CAPiTA)
### ACIP 2014: New Evidence Supporting PCV13 Use Among Adults, CAPiTA Results

<table>
<thead>
<tr>
<th>Study/population</th>
<th>Endpoint</th>
<th>Vaccine Efficacy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPITA ~85,000 Adults 65+ Netherlands</td>
<td>PCV13-serotype IPD</td>
<td>75% (41%, 91%)</td>
</tr>
<tr>
<td></td>
<td>PCV13-serotype non-bacteremic pneumonia</td>
<td>45% (14%, 65%)</td>
</tr>
</tbody>
</table>
Summary Of Evidence Supporting PCV13 Use Among Adults ≥65 Years of Age

- Immune response non-inferior or improved (for some serotypes) for PCV13 (or PCV7) vs. PPSV23\(^1,2\)
- Prevents IPD and non-bacteremic pneumonia\(^3\)
  - 75% reduction in vaccine type IPD
  - 45% reduction in vaccine type non-bacteremic pneumonia
- Safety demonstrated in clinical trials
- Vaccine preventable disease burden remaining among adults ≥65 years
  - Estimated 2,600 PCV13 type IPD cases in 2013\(^4\)
  - Over 50,000 PCV13-type inpatient CAP\(^5\)
- In the short-term, PCV13 likely provides adequate coverage of disease causing serotypes
  - 20-25% IPD due to PCV13 types\(^4\)
  - ~10% of all CAP due to PCV13 types\(^5\)

\(^1\)Phase III trials, Pfizer, ACIP 2011, 2012
\(^2\)DeRoux et al. CID 2008, Goldblatt et al 2009
\(^3\)CAPITA, June 2014 ACIP
\(^4\)Active Bacterial Core Surveillance, 2013
\(^5\)Estimate based on studies using serotype-specific urine antigen test, Pfizer
Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Sara Tomczyk, MSc1,2, Nancy M. Bennett, MD3,4, Charles Stoecker, PhD5, Ryan Gierke, MPH2, Matthew R. Moore, MD2, Cynthia G. Whitney, MD2, Stephen Hadler, MD2, Tamara Pilishvili, MPH2 (Author affiliations at end of text)

On August 13, 2014, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of 13-valent pneumococcal conjugate vaccine (PCV13 [Pneumovax 13, Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer Inc.]) among adults aged ≥65 years. PCV13 should be administered in series with the 23-valent pneumococcal polysaccharide vaccine (PPV23). This report summarizes the evidence supporting ACIP’s recommendation. The evidence supporting PCV13 vaccination of adults was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and determined that evidence was strong in relation to the recommendation whereas evidence was moderate in relation to the ACIP recommendation. The literature continues the strong recommendations for PCV13 use in adults aged ≥65 years and summarizes the evidence on the effectiveness of PCV13 compared with PPV23 in this age group. PCV13 is not indicated for adults aged <65 years; clinical trials are needed in this population.
Pneumococcal Vaccine in Adults ≥65 Years Old (ACIP, 2014)

- Adults 65 years of age or older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23.
  - A dose of PPSV23 should be given 6 to 12 months following a dose of PCV13.

- Adults 65 years of age or older who have not previously received PCV13 and who have previously received one or more doses of PPSV23 should receive a dose of PCV13.
Issues

- Complicated two-dose recommendation
  - Timing

- Stocking of PCV-13 by adult medicine providers

- Medicare coverage of only one dose in a lifetime (either formulation allowed), except with special risk
Pneumococcal vaccine-naïve persons aged ≥65 years

PCV13 at age ≥65 years → PPSV23

6–12 months*

Persons who previously received PPSV23 at age ≥65 years

PPSV23 already received at age ≥65 years → PCV13

≥1 years

Persons who previously received PPSV23 before age 65 years who are now aged ≥65 years

PPSV23 already received at age <65 years → PCV13 at age ≥65 years → PPSV23

6–12 months*  ≥1 years  ≥5 years
Meningococcal Disease Incidence by Serogroup and Vaccine Coverage, United States, 1993-2012

1Source: ABCs cases from 1993-2012 estimated to the U.S. population with 18% correction for under reporting
2National Immunization Survey – Teen; 2006-2012
Serogroup Distribution of Organization-Based Cluster-Associated vs. Sporadic Meningococcal Cases, 2009-2013

- **Organization-based** (n=59)
  - Y: 60%
  - W: 20%
  - C: 10%
  - B: 10%
  - A: 0%

- **Sporadic cases** (n=2431)
  - Y: 50%
  - W: 20%
  - C: 10%
  - B: 10%
  - A: 10%

*Sporadic cases with known serogroup reported to NNDS and not reported in association with a cluster.*
Meningococcal Vaccines

- **Conjugate vaccines**
  - **Menactra (MCV4-D)**
    - Approved for use in those 9 months–55 years, IM
    - A,C,Y,W-135 conjugated to diphtheria toxoid
    - Does not require reconstitution
  - **Menveo (MCV4-CRM)**
    - Approved for use in those 2 months–55 years, IM
    - A,C,Y,W-135 conjugated to CRM197
    - Requires reconstitution

- **Polysaccharide vaccine (MSPV4)**
  - Licensed in 1978, for use in those ≥ 2 years of age, SC
  - Polysaccharide from A,C,Y,W-135
  - Requires reconstitution

- **Non-Capsular**
  - **Trumenba (recombinant lipidated factor H binding protein (fHBP))**
    - Licensed October 29, 2014
    - Approved for use in 10 through 25 years old
    - Surface proteins of B
Meningococcal Vaccine Recommendations

- Routine vaccination of all persons aged 11-18 years with conjugate at the earliest opportunity
- MCV4 should be used in persons 2-10 years recommended to receive meningococcal vaccine
- Conjugate vaccine may be used in persons 11-55 years, polysaccharide vaccine should be used for higher-risk persons >55 years
- Conjugate vaccine also recommended for higher-risk persons aged 19-55 years:
  - college freshmen living in dorms
  - microbiologists routinely exposed to isolates of *N. meningitidis*
  - military recruits
  - travelers to or residents in countries in which *N. meningitidis* is hyperendemic or epidemic
  - those with terminal complement component deficiency or functional or anatomic asplenia (2 doses)
  - those with HIV infection “may elect vaccination”
Booster Dose Schedule

- Ages 11 to 18:
  - At age 16, if primary dose at age 11 or 12 years
  - At age 16 through 18, if primary dose at age 13 through 15 years
  - No booster needed if primary dose on or after age 16 years

- At-risk, ages 2 to 55:
  - Persons aged 2 through 6 years: after 3 years
  - Persons aged 7 years or older: after 5 years
Hepatitis B Vaccination: Diabetics*

- Persons with diabetes who use glucose monitors are at increased risk of hepatitis B virus (HBV) infection
- Risk of acute HBV infection increased in diabetics
  - Age 23-59 yrs: elevated risk 2.1
  - Age ≥ 60 yrs: elevated risk 1.8
- Morbidity and mortality of hepatitis B and diabetes
  - Hep B seroprevalence 60% higher in diabetics
  - Diabetes alone assoc with nonalcoholic fatty liver disease
  - Increased case fatality rate if have hep B and diabetes: 5% vs 2%
- Age at diagnosis of diabetes: 60% at < 60 years
- Cost-effectiveness: $75,100 per quality adjusted life year saved (QALY) saved for those < 60 yrs

* Off-label. MMWR 2011: 60(50);1709
Vaccine decreases herpes zoster by 51%

Vaccine decreases post-herpetic neuralgia by 67%

Available at: [http://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf)
Core recommendations can be found on pages 19-22.
Zoster Vaccine

- Merck’s ZOSTAVAX® licensed on May 25, 2006
- 14-fold more potent than varicella vaccine (19,400 PFU /dose), but the same Oka/Merck strain
- For use in those ≥ 60 years of age to prevent (but not treat) shingles and post herpetic neuralgia
  - Including those with a history of shingles
- Licensed for ≥ 50 y.o. (no change in ACIP recommendation)
- Single dose 0.65 mL given SQ

Challenges to primary care providers:
  - ~$150 per dose, purchase in quantities of 5 doses
  - MUST be stored at -15°C (+5°F) or colder
  - Use within 30 minutes of reconstitution
  - Vaccine shortages
  - Medicare part D

*Aging of acellular cohort (born ≥ 1998)

2004 2010 2012

*2012 data are provisional

SOURCE: CDC, National Notifiable Diseases Surveillance System
Use of Tdap to Protect Infants ‘Cocoon Strategy’

- Adults who have or who anticipate having close contact with an infant aged <12 months should receive a single dose of Tdap
  - Ideally give ≥ 2 weeks before contact with the infant.
- Infants should receive DTaP on schedule
- When possible, women should receive Tdap before conception
- Pregnant women should receive Tdap in the immediate post-partum period
- “Although pregnancy is not a contraindication for receiving Tdap vaccine, health-care providers should weigh the theoretical risks and benefits before choosing to administer Tdap vaccine to a pregnant woman”
Cocooning

- Limited success in immunizing fathers and other family contacts
- Many contacts not identified *a priori*
- Delay in production of protective antibodies
- Effectiveness not established
- Still likely to provide indirect protection
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

In October 2011, in an effort to reduce the burden of pertussis, the United States has experienced a substantial increase in reported pertussis cases over the past several years. Pertussis case counts for 2012 have surpassed the last peak year with 41,886 pertussis cases and 14 deaths in infants age <12 months (2)(CDC, unpublished data, 2012). To reduce the burden, optimizing the current vaccination program is imperative for protecting infants who are at highest risk for death are important. Since in 2011, ACIP vaccination recommendations for pregnant women have been published. A recent survey of 1,234 women (August-October 2011) estimated that only 28% of women received Tdap during their pregnancy (3). New data indicate that maternal antibodies are short-lived; therefore, Tdap vaccination in pregnancy will not provide high levels of antibodies to newborns during subsequent pregnancies (4).

On October 24, 2012, ACIP voted to recommend use of Tdap during every pregnancy. This recommendation did not call for vaccinating pregnant women previously vaccinated with Tdap. This recommendation was based upon the following rationale:

- The 2011 Tdap recommendations did not address the issue of pregnant women who have already been vaccinated with Tdap at a previous gestation. This recommendation was designed to address this gap.
- The benefit of Tdap vaccination during pregnancy outweighs the potential risks for the infant and the mother during the third trimester of pregnancy.
- The benefit of Tdap vaccination during pregnancy is supported by evidence that shows it is safe and efficacious for pregnant women.

Methods

MMWR 2013; 62(7); 131.
TDap Given at Every Pregnancy
Rationale

- TDap vaccination rates in adolescents and adults very low and pertussis disease incidence high
- Maternal antibodies from women immunized before pregnancy waned quickly (Healy 2013 CID)
  - Maternal antibodies short lived
  - Vaccination in one pregnancy unlikely high enough to provide passive protection to infants in subsequent pregnancies
- New mathematical models show vaccination during pregnancy far superior in prevention vs vaccination post partum
  - Best way to protect infants too young to be vaccinated

MMWR 2013; 62(7);131.
Tdap Vaccination Recommended with Every Pregnancy *

- Providers of prenatal care should implement systematic Tdap vaccination programs

- A dose of Tdap should be given during each pregnancy, regardless of the patient’s prior history of receiving Tdap.

- Optimal timing for Tdap is between 27 and 36 weeks gestation
  - Maximizes maternal antibody response and passive antibody transfer to infant
  - But, Tdap may be given at any time during pregnancy

- If Tdap not given during pregnancy, administer immediately postpartum

* Off Label. MMWR 2013; 62(7);131.
Incidence of laboratory-confirmed pertussis by age group, England and Wales, 1998–2012

Source: Health Protection Agency.
Vaccine Effectiveness of Maternal Pertussis Immunization in Preventing Pertussis in Infants Less Than 3 Months of Age

60% coverage
Infants < 3 mos.:
Cases: 407 to 85, -79%
Deaths: 14 to 3, -79%
ACIP Recommendations for Tdap in Adults

- For adults aged 19 years and older who previously have not received a dose of Tdap, a single dose of Tdap should be given.
- Tdap should be administered regardless of interval since the last tetanus or diphtheria toxoid-containing vaccine.
- Adults should receive a Tdap dose, if the dose is recommended and no record of previous administration exists.
- Pregnant women should receive a dose of Tdap during every pregnancy.
Human Papillomavirus Vaccination
Recommendations of the Advisory Committee on Immunization Practices (ACIP)
Rapid acquisition of HPV in following sexual debut

- Study of 18-23 year-old males (n=240)
- Study of female college students (N=603)

**HPV4**: Recommendations

- **Routine 3-dose vaccination with HPV4 for both females and males at 11–12 years**
  - 0.5 mL administered IM
  - 2nd and 3rd doses 2 and 6 months after 1st dose
  - Can be administered with other vaccine
  - Can be administered as early as 9 years of age

- **Catch up vaccination for females:**
  - recommended for 13–26 years

- **Catch-up vaccination for males:**
  - Catch-up vaccination recommended for males 13–21 years
  - Catch-up for high risk males recommended through 26 years (immunosuppressed males, men who have sex with men, and HIV+)
  - Permissive catch-up for other non-high risk males 22-26 years

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1 MMWR 2011; 60 (No. 50)  
2 HPV2 is also approved for females
Per-protocol efficacy for prevention of human papillomavirus vaccine-type disease outcomes among females in trials of the bivalent and quadrivalent human papillomavirus vaccines, end-of-study analyses

Per-protocol efficacy of quadrivalent human papillomavirus vaccine for prevention of HPV 6-, 11-, 16-, and 18-related disease among males aged 16–26 years

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Vaccine</th>
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<tbody>
<tr>
<td></td>
<td>No.</td>
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<td>Genital warts†</td>
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<td>194</td>
<td>3</td>
<td>208</td>
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</table>
From 2007, free HPV vaccine for all women <21 y.o.