Adult Vaccination Update

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April 2014
Where are we with Vaccination of Adults?

The National Health Interview Survey in 2012 reports:

• Only 14% of adults 19 years or older received Tdap vaccine.
  – Over 48,000 cases of pertussis were reported in 2012

• Only 20% of adults 60 years or older received zoster vaccine.

• Only 20% of adults 19 to 64 years at high risk received pneumococcal vaccine.
  – There were approximately 32,000 cases of invasive pneumococcal disease in 2012
## 2014 Recommended Vaccines for Adults

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>WHO NEEDS IT</th>
<th>NUMBER OF DOSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seasonal Influenza</td>
<td>ALL Adults</td>
<td>1 dose every year</td>
</tr>
<tr>
<td>Td</td>
<td>ALL Adults</td>
<td>1 dose every 10 years</td>
</tr>
<tr>
<td>Tdap</td>
<td>ALL Adults who have not received a dose since age 11 or older</td>
<td>1 dose (All)</td>
</tr>
<tr>
<td></td>
<td>Women should receive during every pregnancy</td>
<td>1 dose each</td>
</tr>
<tr>
<td>Pneumococcal Polysaccharide</td>
<td>Adults 65 years or older</td>
<td>1 dose</td>
</tr>
<tr>
<td></td>
<td>Adults 64 years or younger with certain medical conditions and who are at higher risk of infection</td>
<td>1 or 2 doses</td>
</tr>
<tr>
<td>Pneumococcal Conjugate</td>
<td>Adults with certain medical conditions (asplenia, sickle cell disease, cerebrospinal fluid leaks, cochlear implants, or conditions that cause weakening of the immune system)</td>
<td>1 dose</td>
</tr>
<tr>
<td>Zoster</td>
<td>Adults 60 years or older</td>
<td>1 dose</td>
</tr>
<tr>
<td>Hep B</td>
<td>Adults who have not had the vaccine series and who are at risk, including adults with diabetes, end-stage kidney disease, chronic liver disease, or behaviors that increase risk</td>
<td>3 doses</td>
</tr>
</tbody>
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<tr>
<td>HepA</td>
<td>Adults who are at risk and have not had the vaccine series</td>
<td>2 doses</td>
</tr>
<tr>
<td>Hib</td>
<td>Adults with special health conditions (sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or cancer treatment with drugs) who have not already had the vaccine</td>
<td>1 dose</td>
</tr>
<tr>
<td>HPV</td>
<td>Adults 26 years or younger who have not started or finished the vaccine series</td>
<td>3 doses</td>
</tr>
<tr>
<td>MMR</td>
<td>Adults born during or after 1957 who have not had the vaccine or do not have documented evidence of immunity</td>
<td>1 or 2 doses</td>
</tr>
<tr>
<td>Varicella</td>
<td>Adults who have not had chickenpox or do not have documented evidence of immunity</td>
<td>2 doses</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Adults who have not had the vaccine and are at risk for exposure or have damaged spleen</td>
<td>1 or more doses</td>
</tr>
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</table>
Immunization Update - Tdap

- At its October 2012 meeting, the ACIP voted to recommend that healthcare personnel administer a dose of Tdap vaccine to pregnant women during each pregnancy—ideally at between 27 and 36 weeks’ gestation—regardless of the woman’s prior history of receiving Tdap.
  - Reported cases of pertussis have spiked
  - Youngest infants are the most vulnerable
  - Vaccinating the mother during pregnancy can protect the youngest infants.
  - Tdap given at one pregnancy provides insufficient protection for subsequent pregnancies
  - Data support the safety of Tdap for pregnant women and their infants.

The CDC is expected to publish these recommendations in MMWR 2-22-2013
Influenza Vaccines for 2013-14

• Influenza formulation changes for the 2013-2014 vaccine have been announced. Trivalent vaccine (IIV3) will cover:
  – A/California/7/2009 (H1N1)-like virus; (H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011; and B/Massachusetts/2/2012-like virus.

• Quadrivalent vaccine (IIV4) will also include additional B virus coverage:
  – B/Brisbane/60/2008-like virus
  – Note that the FDA must first approve any changes before they can be made
Recently-FDA approved Influenza Vaccines for 2013-14 Season

• Quadrivalent Live-attenuated Influenza Vaccine (LAIV4)—Flumist Quadrivalent (MedImmune) age 2-49 (2 influenza A and 2 influenza B strains)

• Quadrivalent Inactivated Influenza Vaccine (IIV4)—Fluarix Quadrivalent (GSK) age 3 and older and Fluzone Quadrivalent (Sanofi) age 6 mo and older both have (2 influenza A and 2 influenza B strains)

• Cell-culture based inactivated influenza vaccine (cclIIV3)—Flucelvax (Novartis) age 18 and older

• Recombinant hemagglutinin vaccine (RIV3)—FluBlok (Protein Sciences) age 18-49
Existing Influenza Vaccines for 2013-14?

- Fluvirin – II3/TIV by Novartis age 4 yrs and up
- FluLavel – II3/TIV by GSK age 18 yrs and up
- Afluria – II3/TIV by Merck age 9 yrs and up
- Fluzone High Dose – II3/TIV by Sanofi age 65 and older
- Fluzone Interdermal – II3/TIV by Sanofi age 18 to 64 yrs
FDA approves Flucelvax by Novartis

• November 20, 2012 The U.S. Food and Drug Administration announced today the approval of Flucelvax, the first seasonal influenza vaccine licensed in the United States produced using cultured animal cells, instead of fertilized chicken eggs. Flucelvax is approved to prevent seasonal influenza in people ages 18 years and older.

• The manufacturing process for Flucelvax is similar to the egg-based production method, the virus strains included in the vaccine are grown in animal cells of mammalian origin instead of in eggs. Cell culture technology has already been in use for several decades to produce other U.S. licensed vaccines (polio, rubella and hepatitis A).

• A “subunit” influenza virus vaccine prepared from virus propagated in Madin Darby Canine Kidney (MDCK) cells.
Flublok by Protein Sciences Corporation

- Flublok (Influenza Vaccine) Sterile Solution for Intramuscular Injection contains purified HA proteins produced in a continuous insect cell line (expresSF+®) that is derived from Sf9 cells of the fall armyworm, Spodoptera frugiperda, and grown in serum-free medium composed of chemically-defined lipids, vitamins, amino acids, and mineral salts.
- Flublok is approved for use in persons 18 through 49 years
- Flublok has a shorter shelf life, with an expiration period of 16 weeks from the production date, as compared to currently available inactivated influenza vaccines which carry an expiration date of June 30
  - For the 2012 - 2013 influenza season it is formulated to contain 135 mcg HA per 0.5 mL dose, with 45 mcg HA of each of the following 3 influenza virus strains: A/California/7/2009 (H1N1), A/Victoria/361/2011 (H3N2), and B/Wisconsin/1/2010. FDA approval 12-21-2012
Influenza Vaccine in Patients with Egg Allergy?

• The American College of Allergy, Asthma and Immunology "The very low risk of reacting to the injection is greatly outweighed by the risks associated with the flu."

• ACAAI recommends that those with a previous history of egg allergy get the injectable vaccine in a medical facility where any allergic emergencies can be recognized and treated if they occur. For those who have had serious reactions after eating eggs, the vaccine should be administered in an allergist's office.

• In the past, there was concern that because the flu vaccine is grown in eggs, residual protein could trigger a reaction in those with allergies.
Influenza Vaccine in Patients with Egg Allergy?

• June 21, 2012 The ACIP meeting marked the 1-year anniversary of a change in recommendations that removed egg allergy as a contraindication to influenza vaccination, and it does not appear that the modification affected the rate of allergic reactions, according to data from the Vaccine Adverse Event Reporting System (VAERS).
Influenza Vaccine in Patients with Egg Allergy?

• June 20, 2013 the ACIP recommended Protein Science's FluBlok for the 2013-14 season in a 13 to 0 vote for patients with a history of egg allergy.

  – A recently approved cell-based flu vaccine Flucelvax, made by Novartis, uses flu viruses grown in mammalian cells rather than chicken eggs and is thought to contain hardly any traces of egg. However, the vaccine seed strain used to make the vaccine is passaged in eggs, meaning it could contain a minuscule amount of albumin.
Influenza Vaccine Efficacy

• Interim results for the 2013–14 season indicate that vaccination has reduced the risk for influenza-associated medical visits by approximately 60%. (MMWR 2-21-2014)
ACIP Meeting 10-25-2013

• Fluzone High-Dose was 24.2% more effective in preventing influenza in 32,000 adults aged 65 years or older than regular Fluzone in a large-scale 2 year clinical trial conducted in the US and Canada, vaccine maker Sanofi Pasteur told the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention today.

• The rate of laboratory-confirmed influenza among participants receiving Fluzone High-Dose was 1.43% compared with 1.89% among patients immunized with Fluzone. For the FDA to deem Fluzone High-Dose as superior, the vaccine needed to demonstrate a relative efficacy rate of at least 9.1%. It achieved a rate more than twice that — 24.2%
H5N1 Avian Influenza Vaccine

• Nov 22, 2013 Vaccine to supplement National Stockpile, not intended for commercial availability but it is intended to be made available to the public in a pandemic outbreak.

• The vaccine, Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, is for use in people 18 years of age and older who are at increased risk of exposure to the H5N1 avian influenza virus.
H5N1 Avian Influenza Vaccine

• Most avian influenza A viruses do not infect people. However some viruses, such as H5N1, have caused serious illness and death in people outside of the U.S., mostly among people who have been in close contact with infected and ill poultry. When people do become infected with H5N1, about 60 percent die, according to the World Health Organization.
H5N1 Avian Influenza Vaccine

• The vaccine is made using an egg-based manufacturing process, which is also used for ID Biomedical Corporation’s seasonal influenza vaccine, FluLaval.
  – It contains the adjuvant AS03, an oil-in-water emulsion to enhance the immune response of the vaccinated individual. The adjuvant makes it possible to use a small amount of influenza protein per dose of vaccine to elicit the desired immune response in an individual to prevent influenza disease. Reducing the amount of influenza protein per dose.
H5N1 Avian Influenza Vaccine

• The H5N1 component and the AS03 adjuvant component are supplied in two separate vials, which must be combined prior to use. The vaccine is administered via intramuscular injection in two doses, 21 days apart.

• Safety data comes from approximately 3,400 adults 18 years of age and older
  – Muscle aches, headache, fatigue and injection site pain, redness and swelling were common.
Comparison of *S. pneumoniae* serotype coverage between PCV13 and PPSV23

Vaccine Serotypes included

- Both PPSV23 and PCV13: 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
- PPSV23 only: 2, 8, 9N, 10A, 11A, 12F, 15B, 17F, 20, 22F, 33F
- PCV13 only: 6A

- The most notable difference between PCV13 and PPSV23 is the *S. pneumoniae* serotypes covered by each of the vaccines. Although PCV13 provides protection against fewer *S. pneumoniae* serotypes than PPSV23, PCV13 has been shown to be noninferior to PPSV23 in functional antibody response.
Polysaccharide vs. Conjugate Polysaccharide Vaccines

**Polysaccharide**
- Stimulate T-cell independent immunity
- Stimulate B cells without assistance of T helper cells
- Short-lived immunity
- No booster effect
- Not consistently immunogenic in children <2 y/o

**Conjugate Polysaccharide**
- Stimulate T-cell dependent immunity
- T helper cells involved
- Produce immunologic memory
- Result in booster effect upon subsequent exposure
- Increased immunogenicity in children <2 y/o
The Impact of Pneumococcal Vaccine

• In the United States, widespread use of PCV7, a protein conjugate pneumococcal vaccine that contains polysaccharides from seven serotypes that commonly colonized and infected young children, was followed by a >90 percent reduction in invasive disease caused by vaccine serotypes in both children and adults.

• However, "replacement strains" (ie, strains that are not contained in PCV7) have increased in prevalence; some of these strains, such as serotypes 19A and 6A, have very high rates of penicillin resistance. The newer 13-valent pneumococcal vaccine, PCV13, includes polysaccharides from serotypes 19A and 6A, so disease caused by these types is expected to become much less common.
Pneumococcal Conjugate Vaccine 13-valent (PCV13)

- Prevnar 13 (Wyeth/Pfizer)
  - Replaces PCV7
- Indicated for the active immunization of children ages 6 weeks to 5 years old
  - For the prevention of invasive disease caused by 13 *Streptococcus pneumoniae* serotypes
  - For the prevention of otitis media caused by 7 *Streptococcus pneumoniae* serotypes
- FDA approved for adults aged 50 years and older (Not ACIP recommended for routine use)
- Dose and route: 0.5 mL IM
Pneumococcal Conjugate Vaccine 13-valent (PCV13)

- Target groups for vaccination
  - Infants and children
- Routine schedule: 2, 4, 6 mo and a booster at 12–15 months
  - Any PCV series begun with PCV7 should be completed with PCV13
- Administer a single supplemental dose of PCV13 for:
  - Children aged 14–59 months who have received an age-appropriate series of PCV7
  - Children aged 60–71 months with underlying medical conditions who have received an age-appropriate series of PCV7
Pneumococcal Polysaccharide Vaccine 23-valent (PPSV)

- Pneumovax 23 (Merck)
  - Protects against 85%–90% of serotypes known to cause invasive disease
  - Reduces the risk of invasive disease by 60%–70%
  - More efficacious against bacteremia than pneumonia
  - Not adequately effective in people <2 y/o
Pneumovax 23

• What route and needle length is recommended for administration of pneumococcal polysaccharide vaccine?
  – Pneumococcal polysaccharide vaccine may be given either by intramuscular (IM) or subcutaneous (SC) injection. When administration is IM, choose needle length appropriate to the person's age and body mass: toddlers age 2 yrs: 1–1¼" (anterolateral thigh) or ⅝–1" (deltoid muscle); children ages 3–4 yrs: ⅝–1" (deltoid) or 1–1¼" (anterolateral thigh); adults, a 1–1½" needle. A ⅝" needle may be used in toddlers and children and for adult patients weighing less than 130 lbs (60 kg) for IM injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle. When administration of PPSV23 is SC, a ⅝" needle is recommended.
Revaccination With PPSV

- Revaccinate these people:
  - People ≥65 y/o who received initial dose(s) ≥5 years ago and when <65 y/o
  - People 2–64 y/o at highest risk of death (e.g., asplenia, immunosuppression, sickle cell disease), who received initial dose ≥5 years ago
Pneumococcal Vaccines Adverse Reactions

• Local reactions (pain, swelling and redness)
  – polysaccharide - 30%-50%
  – conjugate - 5%-49%

• Fever, myalgia
  – polysaccharide - <1%
  – conjugate - 24%-35% (more common with 4\textsuperscript{th} dose)

• Severe adverse reactions - rare
Costs

- Pneumovax 23 $61.75 each dose WAC
- Prevnar 13 $126.83 each dose WAC
Pneumococcal Vaccines

- If patients who are in a recommended risk group for PPSV23 or PCV13 aren't sure if they have previously received these vaccines, should healthcare providers vaccinate them?
  - Yes. If patients do not have a documented vaccination history for these two vaccines and their records are not readily obtainable, you should administer the recommended doses. Extra doses will not cause harm to the patient.
FDA Okays Pneumococcal Vaccine for Older Adults

- December 20, 2011 The FDA approved the pneumococcal 13-valent conjugate vaccine (manufactured by Wyeth Pharmaceuticals, marketed by Pfizer Inc) for adults aged 50 years and older for the prevention of pneumonia and invasive disease caused by the 13 Streptococcus pneumoniae serotypes contained in the vaccine.

- The move comes on the heels of the November 16, 2011, meeting of the FDA's Vaccines and Related Biologics Advisory Committee, in which the committee voted 14 to 1 in favor of expanding the indication for Prevnar 13 to adults.
CDC Recommends Immunocompromised Adults Get Prevnar 13 Vaccine

• June 21, 2012 the Centers for Disease Control and Prevention's Advisory Committee on Vaccine Practices voted 14 to 0 that adults "with AIDS, cancer, organ transplants, advanced kidney disease and other immune-weakening conditions" should be given pneumococcal vaccine Prevnar 13, including those "who've already had Pneumovax 23" The panel has not yet decided if "all adults 50 years old and older should get Prevnar 13."
ACIP Recommendations for PCV13 and PPSV23 Use

• Adults with specified immunocompromising conditions who are eligible for pneumococcal vaccine should be vaccinated with PCV13 during their next pneumococcal vaccination opportunity.

• Pneumococcal vaccine-naïve persons. ACIP recommends that adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose.

— MMWR October 12, 2012 / 61(40);816-819
ACIP Recommendations for PCV13 and PPSV23 Use

• **Previous vaccination with PPSV23.** Adults aged ≥19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, who previously have received ≥1 doses of PPSV23 should be given a PCV13 dose ≥1 year after the last PPSV23 dose was received. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23.

  – MMWR October 12, 2012 / 61(40);816-819
The 85,000-patient study in the Netherlands, called CAPiTA, showed that Prevnar 13 prevented invasive pneumococcal disease, meaning infections of Streptococcus pneumoniae bacteria in patients age 65 and older.

- 45.56% fewer first episodes of vaccine-type CAP among Prevenar 13-vaccinated subjects than in subjects who received placebo (P=0.0006).
- Secondary objectives, the Prevenar 13 group experienced 45.00% fewer first episodes of non-bacteremic/non-invasive vaccine-type CAP (P=0.0067) and 75.00% fewer first episodes of vaccine-type IPD (P=0.0005) compared with the placebo group.
Zoster Vaccine

- Zostavax (Merck)
  - Live attenuated virus vaccine
  - Higher strength than varicella vaccine (Each 0.65-mL dose contains a minimum of 19,400 PFU (plaque-forming units) of Oka/Merck strain of VZV)
- ACIP target group for vaccination
  - Adults ≥60 y/o
- FDA approved indication
  - Adults ≥50 y/o
  - Note: ACIP recommendations still are for 60 years and above and do not support 50-59 years for routine use.
- Dose and route
  - 0.65 mL (entire contents of vial) SC
Varicella Vaccine

- Before reconstitution, store the lyophilized vaccine in a freezer at a temperature between \(-58^\circ F\) and \(+5^\circ F\) \((-50^\circ C\) and \(-15^\circ C\))
- VARIVAX may be stored at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2°C to 8°C which is not used within 72 hours of removal from +5°F (-15°C) storage should be discarded.
  - Store diluent at room temperature or in refrigerator but do not freeze.
- Before reconstitution, protect from light.
- DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES

Cost: $98.64 per single dose vial
Zoster Vaccine

• Do not administer to immunosuppressed or immunodeficient individuals including those with a history of primary or acquired immunodeficiency states, leukemia, lymphoma or other malignant neoplasms affecting the bone marrow or lymphatic system, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy.
Zoster Vaccine

March 24, 2011 FDA approved – Zostavax for patients age 50-59 years

• Compared with placebo, ZOSTAVAX significantly reduced the risk of developing zoster by 69.8% (95% CI [54.1 - 80.6%]) in 22,439 subjects 50 to 59 years of age. Data from the Shingles Prevention Study demonstrated 64% (95% CI 56-71%) efficacy in patients age 60-69 years and 41% (95% CI 28 -52%) efficacy for patients age 70-79 years and only 18% (95% CI -29 – 48%) efficacy in patients age 80 and above.
Zoster Vaccine

- June 2011 the ACIP declined to recommend the vaccine for adults aged 50 through 59 years and reaffirmed its current recommendation that herpes zoster vaccine be routinely recommended for adults aged 60 years and older. (supply concerns?)
  - MMWR November 11, 2011 For vaccination providers who choose to use Zostavax among certain patients aged 50 through 59 years despite the absence of an ACIP recommendation, factors that might be considered include particularly poor anticipated tolerance of herpes zoster or postherpetic neuralgia symptoms (e.g., attributable to preexisting chronic pain, severe depression, or other comorbid conditions; inability to tolerate treatment medications because of hypersensitivity or interactions with other chronic medications; and occupational considerations).
Zoster Vaccine

• Patients in the Shingles Prevention Study who developed herpes zoster despite vaccination had a shorter duration and reduced severity of symptoms than those in the placebo group.

• A recent Cochrane Review concluded: “There is insufficient direct evidence from specialized trials to prove the efficacy of vaccine for preventing postherpetic neuralgia beyond its effect on reducing herpes zoster, although vaccination may be efficacious and safe for preventing herpes zoster and thus reduce the incidence of postherpetic neuralgia in adults aged 60 years or older.”
Zoster Vaccine

Adverse Effects:

• Pain 53.9% vs. placebo 9.0%
• Erythema 48.1% vs. 4.3%
• Swelling 40.4% vs. 2.8%
• Pruritus 11.3% vs. 0.7%
• Headache 9.4% vs. 8.2%

Storage of the unreconstituted vaccine is the same as for the Varivax vaccine in the freezer, store diluent either at room temp or in refrigerator not in freezer!

Cost: $173.68 per single dose vial WAC
Zostavax in Patients with a History of Shingles?

• Administration of the varicella vaccine in older people with a recent history of shingles does not confer additional immunity, a population-based study from Kaiser Permanente in Southern California suggests. The findings, published online June 4, 2012 in the Journal of Infectious Diseases, indicate that immediate vaccination may be unwarranted.

• Dr. Oxman, national chairman of VA Cooperative Study #403–The Shingles Prevention Study, but was not involved in the current study made the following comments:
  – "A case of shingles boosts your cell-mediated immunity to the varicella virus. It's clear that [infection] gives you a maximum response to the varicella virus, so giving the vaccine is like bringing coal to Newcastle,"
  – "If I knew for certain that a patient had a real case of shingles with plenty of blisters indicating plenty of virus and virus antigen, I would tell them to wait 2 or 3 years [before receiving the vaccine]."
Herpes Zoster Vaccine Persistence?

- The Shingles Prevention Study (SPS; Department of Veterans Affairs Cooperative Study 403) demonstrated that zoster vaccine was efficacious through 4 years after vaccination. The Short-Term Persistence Substudy (STPS) was initiated after the SPS to further assess the persistence of vaccine efficacy.
- There is evidence of the persistence of vaccine efficacy through year 5 after vaccination but, vaccine efficacy is uncertain beyond that point.
Controversy?

• The Zostavax vaccine (Merck) package insert and the FDA say that Zostavax should not be given simultaneously with pneumococcal polysaccharide vaccine (PPSV23) while the ACIP and CDC say that they can be administered at the same time?
From the Zostavax PI

• In a double-blind, controlled clinical trial, 473 adults, 60 years of age or older, were randomized to receive ZOSTAVAX and PNEUMOVAX 23 concomitantly (N=237), or PNEUMOVAX 23 alone followed 4 weeks later by ZOSTAVAX alone (N=236). At four weeks postvaccination, the VZV antibody levels following concomitant use were significantly lower than the VZV antibody levels following nonconcomitant administration (GMTs of 338 vs. 484 gpELISA units/mL, respectively; GMT ratio = 0.70 [95% CI: 0.61, 0.80]).
In a randomized clinical study, a reduced immune response to Zostavax as measured by gpELISA was observed in individuals who received concurrent administration of Pneumovax 23 and Zostavax compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks.
Observational Study

Kaiser Permanente Southern California conducted an observational study to evaluate if concomitant vaccination with the polysaccharide pneumococcal vaccine reduces the protective effect of the zoster vaccine.

• The incidence of herpes zoster (HZ) after vaccination with a zoster vaccine in the population receiving both vaccines on the same day was compared to that in the population receiving a pneumococcal vaccine within one year to 30 days prior to zoster vaccine. Vaccinations and incident HZ cases were identified by electronic health records.

• The hazard ratio for incident HZ associated with concomitant vs. nonconcomitant vaccination was estimated using the Cox proportional hazard model. There were 56 incident HZ cases in the concomitant vaccination cohort and 58 in the nonconcomitant vaccination cohort, yielding a HZ incidence of 4.54 (95% confidence interval [CI], 3.43–5.89) and 4.51 (95% CI, 3.42–5.83) per 1000 person-years, respectively.

• The hazard ratio comparing the incidence rate of HZ in the two cohorts was 1.19 (95% CI, 0.81–1.74) in the adjusted analysis.

• In this study, we found no evidence of an increased risk of HZ in the population receiving zoster vaccine and pneumococcal vaccine concomitantly.
  — Vaccine 2011; 29:3628-32
ACIP Recommendation

• What does ACIP say about this?
  – ACIP has not changed its recommendation on the simultaneous administration of these two vaccines (i.e., they can be given at the same time or any time before or after each other)
There are more than 100 strains of HPV, and while most cases of HPV infection usually resolve on their own, there are more than 40 strains that can cause cancer. Overall, HPV is related to almost 100% of cervical cancer cases. While cervical cancer is the main concern with HPV, the disease is also known to cause oral, anal, vulvar, vaginal and penile cancers, as well as genital warts.

It is estimated that 50% of sexually active men and women will get HPV at some point in their lives.
HPV Vaccines

• Gardasil®, produced by Merck, prevents infection of four strains of HPV—6, 11, 16, and 18—and was approved by the FDA in 2006.15

• GlaxoSmithKline’s vaccine, Cervarix®, was approved by the FDA in 2009 and protects against HPV strains 16 and 18. Unlike Gardasil, Cervarix can only be administered to females and does not protect against genital warts.16,17

• HPV strains 16 and 18 are associated with 70% of cervical cancer cases, while strains 6 and 11 are associated with 90% of genital warts cases.18 Both vaccines have been shown to protect against vulvar and vaginal cancers, and Gardasil also protects against HPV-associated anogenital diseases.
HPV Vaccine

• ACIP recommends that all girls and boys get vaccinated at age 11 or 12, and that girls and women ages 13-26 and boys and men ages 13-21 be given a “catch-up” vaccination. The vaccine is recommended for use in men ages 22-26 if they have not been previously vaccinated or are immunocompromised.

• These recommendations are designed to promote vaccination before the initiation of sexual activity and exposure to HPV, when the vaccine is most effective. Those already infected with HPV can benefit from the vaccine because it can prevent infection against HPV strains they may not have contracted, but the vaccine does not treat existing HPV infections.
HPV Vaccine

• When a provider strongly recommends HPV vaccination, patients are 4 to 5 times more likely to receive HPV vaccine. It is time for physicians and other health care providers to strongly recommend HPV vaccine to prevent cervical and other cancers.

• Both vaccines are currently administered in 3 doses over 6 months (0, 1-2 and 6 mo), but research is under way as to whether 2 doses may be sufficient to provide protection. ($130.00/dose)
HPV Vaccine

• Four leading national medical associations— the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American College of Obstetricians and Gynecologists (ACOG)—together with the Immunization Action Coalition (IAC) and the Centers for Disease Control and Prevention (CDC), have issued a call to action, urging physicians across the United States to educate their patients about human papillomavirus (HPV) vaccine, and to strongly recommend HPV vaccination.
HPV Vaccine

• Despite more than seven years of vaccine monitoring showing overwhelming evidence of HPV vaccine safety and effectiveness, HPV vaccination rates are not improving while rates for other adolescent vaccines are.
• In 2012 only 33% of female adolescents age 13-17 had received all three doses and only 7% of boys and young men had received all three doses.
• In the United States alone, 79 million people are currently infected with HPV. Every year, 14 million are newly infected and 26,000 cancers attributable to HPV are diagnosed.
Meningitis type B

• Meningitis type B is responsible for about a third of U.S. meningitis cases, but is the only strain not currently preventable by an FDA-approved vaccine.

• In the last year MenB has infected more than a dozen students at Princeton, UC-Santa Barbara, and Drexel.

• MenB is a potentially deadly disease which is easily misdiagnosed and can kill within 24 hours of onset. About one in 10 of those who contract the disease will die despite appropriate treatment. Up to one in five survivors may suffer from devastating, life-long disabilities such as brain damage, hearing impairment or limb loss.
Meningitis type B Vaccine

- Bexsero®, a multi-component Meningococcal B (MenB) vaccine (recombinant, adsorbed) suspension for injection 0.5 ml pre-filled syringe by Novartis is under review at the FDA.
- Safety and efficacy have been shown through clinical trials involving more than 8,000 people including infants, children, adolescents and adults.
- Available in Canada, EU and Australia.
Vaccine Storage and Handling

• Pneumococcal polysaccharide vaccine should be shipped in an insulated container with coolant packs. The vaccine should be stored at refrigerator temperature (35°–46°F [2°–8°C]).
• Pneumococcal conjugate vaccine should be stored at refrigerator temperature. Pneumococcal vaccines must not be frozen.
• Opened multidose vials may be used until the expiration date printed on the package if they are not visibly contaminated.
Regulation 61-120 - South Carolina Immunization Registry

• Mandatory to report administered immunizations to the South Carolina Immunization Registry as of Jan 1, 2014 with in 10 days of administration.

• Immunization providers who must register include any individual healthcare provider licensed, certified, registered or otherwise authorized by law to provide immunizations, and an organization, facility, or other entity that provides immunizations through such individual providers (in the case of organizations or facilities only the entity must register rather than individuals).
Regulation 61-120 - South Carolina Immunization Registry

Implementation Schedule

• Immunization providers will enter all immunizations into the registry on the following schedule, according to the date of administration and date of birth of the immunized patient:
  – All immunizations administered after December 31, 2013 to children born after December 31, 2013 (less than one year of age), and to adults born before 1946 (69 years of age and older);
  – All immunizations administered after December 31, 2014, to children born after December 31, 2008 (6 years of age and younger), and to adults born before 1950 (66 years of age and older);
  – All immunizations administered after December 31, 2015, to children born after December 31, 2003 (12 years of age and younger), and to adults born before 1961 (56 years of age and older);
  – All immunizations administered after December 31, 2016.

• Immunizations administered before the designated dates are not required to be entered in the registry, but may be entered voluntarily.