2016 Immunization Update
for Pharmacists
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Southern Illinois University Edwardsville
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Disclosure
- Miranda Wilhelm reports:
  • Speaker’s bureau member for Merck Vaccines

  - CEI has taken appropriate action for conflict resolution, including external peer review by an un-conflicted reviewer.

Learning Objectives
- Upon successful completion of this activity, pharmacists should be able to:
  • Discuss the 2016 Advisory Committee on Immunization Practices (ACIP) recommendations regarding adult and pediatric immunizations.
  • Identify true contraindications to receipt of a variety of vaccines.
  • Review influenza vaccine considerations such as nomenclature, characteristics, schedule, contraindications, and precautions in preparation for the 2016-2017 season.
  • Evaluate a patient’s immunization history to determine appropriate vaccine recommendations based on the appropriate immunization schedule.
Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥ 10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2015.


Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of the Advisory Committee on Immunization Practices.

Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B Infected Mothers.

Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015.


Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥ 10 Years at Increased Risk for Serogroup B Meningococcal Disease: MMWR, June 12, 2015; 64(22): 608-612.
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- FDA approved October 29, 2014 (Pfizer)
- Final serogroup B meningococcal vaccine
- Approved for patients 10 to 25 years of age
- 3-dose series, 0.5 mL dose administered at 0, 2 and 6-months apart

- April 14, 2016 FDA Update
  - Two-dose schedule (administered at 0 and 6 months)
  - Modification of 3-dose schedule (0, 1, 2, and 6 months)


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- FDA approved January 23, 2015 (Novartis)
- Second serogroup B meningococcal vaccine
- Approved for patients 10 to 25 years of age
- 2-dose series, 0.5 mL dose administered at least 1 month apart


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Yellow Fever Vaccine Booster Doses

- Single primary dose of yellow fever vaccine provides long-lasting protection and is adequate for most travelers
- 10-year booster dose requirement is no longer relevant
- Consideration and recommendations for booster doses for certain travelers and laboratory workers
**Intervals Between PCV13 and PPSV23 Vaccines**

**Recommendation**
- Harmonized the dosing interval
- All patients at 65 years of age should receive 1 dose of PCV13 followed by 1 dose of PPSV23

**Summary**
- What is currently recommended?
- Why are the recommendations being modified now?
- What are the new recommendations?

**Intervals for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers**

**Recommendation**
- Not ACIP statement but related document from CDC
- For infants born to hepatitis B-infected mothers, postvaccination serologic testing should be completed at age 9-12 months (or 1-2 months after the final dose of the vaccine series).
Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers

**MMWR, October 9, 2015; 64(39): 1118-1120.**

Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults

**Citation**
- Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015.
- MMWR, October 23, 2015; 64(41): 1171-1176.

**Summary**
- What is currently recommended?
- Why are the recommendations being modified now?
- What are the new recommendations?

**Recommendation**
- All adolescents aged 11 or 12 years should receive 1 dose of meningococcal conjugate vaccine (MenACWY) with a booster dose at age 16.
- MenB vaccine series may be administered to adolescents, ages 16-23 years. Preferred for ages 16-18 years.

<table>
<thead>
<tr>
<th>Age at MenB series</th>
<th>Cases prevented</th>
<th>Deaths prevented</th>
<th>NNV to prevent case</th>
<th>NNV to prevent death</th>
<th>Cost per QALY (million $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 yrs</td>
<td>28</td>
<td>2</td>
<td>293,000</td>
<td>1,512,000</td>
<td>8.7</td>
</tr>
<tr>
<td>16 yrs</td>
<td>29</td>
<td>5</td>
<td>102,000</td>
<td>628,000</td>
<td>3.7</td>
</tr>
<tr>
<td>College student</td>
<td>0</td>
<td>1</td>
<td>360,000</td>
<td>2,097,000</td>
<td>9.4</td>
</tr>
</tbody>
</table>
Testing Your Knowledge…

True/False – Meningococcal serogroup B vaccination is recommended for adolescents and young adults with a preference of 16 to 18 years of age.

a) True
b) False

Use of Vaccinia Virus Smallpox Vaccine in Laboratory and Health Care Personnel

Survey

• What is currently recommended?
• Why are the recommendations being modified now?
• What are the new recommendations?

Recommendations

• Routine vaccination with ACAM2000 is recommended for laboratory personnel who directly handle cultures or animals contaminated or infected with vaccinia virus
• Health care personnel who treat patients with vaccinia virus or administer ACAM2000 vaccine can be offered vaccination

Vaccine Storage and Handling Toolkit

• Updated June 2016
• Adjusted CDC guidance on Fahrenheit temperature range for storing refrigerated vaccines
  - NEW = 36°F – 46°F
  - OLD = 35°F – 46°F
• Celsius remains unchanged (2°C – 8°C)
1. Is the child sick today?

- No evidence that acute illness reduces vaccine efficacy or increases vaccine-related adverse events
  - All illnesses other than those noted below (fever, rash, skin, ear, or eye infection, diarrhea, or vomitus) are NOT contraindications.
  - Antibiotics are NOT a contraindication.

- Precaution – moderate or severe acute illness, all vaccines should be delayed.

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- Precaution – moderate or severe acute illness, all vaccines should be delayed.
2. Allergies to medications, food…?
- Must be anaphylaxis and not an intolerance
- Medications
  - Neomycin – DTaP, Hep A, Influenza (Afluria, Fluvirin), MMR, MMRV, IPV, Varicella, Zoster
- Food
  - Gelatin – MMR, MMRV or Varicella
  - Eggs – Influenza?
- Vaccine component
  - Latex
    - Varies – vial or syringe tip cap

3. Serious reaction in the past…?
- History of anaphylactic reaction to a previous dose or vaccine component
- History of encephalopathy within 7 days following pertussis-containing vaccine
- Precautions for DTaP include:
  - Seizure within 3 days of a dose
  - Pale or limp episode or collapse within 48 hours of a dose
  - Continuous crying for 3 or more hours within 28 hours of a dose
  - Fever of 105°F within 48 hours of a dose

4. Health problem or aspirin therapy…?
- Safety of Live Attenuated Influenza Vaccine (LAIV) has not been established for patients with medical conditions
- Risk of Reye’s Syndrome when aspirin and live attenuated vaccines are administered concomitantly
5. Wheezing in a 2 to 4 year old…?
- Increased risk of wheezing following administration of LAIV
- Not listed in package insert
- ACIP recommends children 2 through 4 years of age with wheezing in the past 12 months receive IIV

6. History of intussusception…?
- History of intussusception is a contraindication for rotavirus vaccine

7. Seizure or nervous system problem…?
- History of encephalopathy within 7 days following pertussis-containing vaccine
- History of seizures unrelated to vaccination with MMRV. Should receive separate MMR and VAR vaccines.
- Precaution with history of Guillain-Barré syndrome (GBS) with the following:
  - Td/Tdap: if GBS occurred within 6 weeks of prior tetanus-containing vaccine
  - Influenza: if GBS occurred within 6 weeks of prior dose
8. Current immune system problem...?
- Live virus vaccines are usually contraindicated in immunocompromised patients
- LAIV – inactivated vaccines are available
- MMR – can be used for HIV infected children if no evidence of immunosuppression
- VAR – can be used for HIV infected children if CD4 T-lymphocyte percentage ≥ 15% or greater OR in those <8 years of age or CD4 count is ≥ 200 cells/µL
- RV – severe combined immunodeficiency (SCID), other forms of immunosuppression are precautions

9. Immune suppressing medication...?
- Live virus vaccines are usually contraindicated in immunocompromised patients and should be postponed until after chemotherapy or high-dose steroid therapy.

High-Level
- Receiving cancer chemotherapy
- Within 2 months of solid organ transplantation
- Receiving daily corticosteroid therapy with a dose of ≥ 20 mg of prednisone for ≥ 14 days
- Receiving certain biologic immune modulators (TNF-α blockers)

Low-Level
- Receiving a lower daily dose of corticosteroid therapy for ≥ 14 days
- Receiving methotrexate (MTX) ≤ 0.4 mg/kg/week, azathioprine ≤ 3 mg/kg/day, or 6-mercaptopurine ≤ 1.5 mg/kg/day

10. Blood transfusion...?
- Certain live virus vaccines may have reduced efficacy when administered concurrently with blood products or antiviral drugs and need to be deferred

Recommended intervals between administration of immune globulin preparations and measles-or varicella-containing vaccine.


11. Is the child/teen pregnant...?
- Live virus vaccines are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus
- LAIV – inactivated vaccines available
- MMR – congenital rubella syndrome
- MMRV – congenital rubella syndrome or varicella syndrome
- VAR – congenital varicella syndrome
- IPV – theoretical concerns

MMWR, January 28, 2011; 60(2):1-64.

12. Other vaccines in the past 4 weeks?

- Live virus vaccines when not administered on the same day need to be separated by 28 days
- Inactivated vaccines may be given at the same time or at any spacing interval

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- Inactivated vaccines may be given at the same time or at any spacing interval

Summary of Contraindications

<table>
<thead>
<tr>
<th>All vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe allergic reaction (anaphylaxis) after a previous dose or to a vaccine component</td>
</tr>
<tr>
<td>Pregnancy</td>
</tr>
<tr>
<td>History of intussusception</td>
</tr>
<tr>
<td>Severe combined immunodeficiency (SCID)</td>
</tr>
<tr>
<td>Known severe immunodeficiency</td>
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<table>
<thead>
<tr>
<th>Live attenuated vaccines</th>
</tr>
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<tbody>
<tr>
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<tr>
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<tr>
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<tr>
<td>Age younger than 6 weeks</td>
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<table>
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<tr>
<th>Inactivated vaccines</th>
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<tbody>
<tr>
<td>Severe allergic reaction (anaphylaxis) after a previous dose or to a vaccine component</td>
</tr>
<tr>
<td>Pregnancy</td>
</tr>
<tr>
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Influenza

- Influenza season is October to May and commonly peaks in January to February
- Annual influenza vaccination is recommended for all persons 6 months of age and older
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Testing Your Knowledge...
What volume of inactivated influenza vaccine is administered intramuscularly to an adult patient?
(a) 0.1 mL
(b) 0.25 mL
(c) 0.5 mL
(d) 1 mL

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Nomenclature for Influenza Vaccine

- Inactivated Influenza Vaccine (IIV)
  - Trivalent inactivated influenza vaccine (IIV3)
  - Quadrivalent inactivated influenza vaccine (IIV4)
  - Cell cultured inactivated influenza vaccine (ccIIV3)

- Recombinant Hemagglutinin Influenza Vaccine (RIV)
  - NA

- Live-attenuated Influenza Vaccine (LAIV)
  - Quadrivalent live-attenuated influenza vaccine (LAIV4)

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Influenza Algorithm for Children 6 Months to 8 Years

MMWR, August 7, 2015; 64(30): 818-825.
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Recommendation for Influenza Vaccination with Egg Allergy

MMWR, August 15, 2014; 63(327):691-697.

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Proposed recommendations for 2016-2017:
- LAIV included as an option for individuals with egg allergy of any severity
- Removal of 30 minute post vaccination observation period (15 minutes recommended for all persons, particularly adolescents, in case of syncope occurs)
- Persons with a history of severe reaction to eggs should be vaccinated in a medical setting with a physician immediately available.

Influenza Vaccination of Persons with Egg Allergy


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Influenza
Contraindications / Precautions
- IIV (includes IIV3, IIV4 and ccIIV)
- Contraindications
  - History of severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine
  - Precautions
  - Moderate to severe illness with or without fever
  - History of Guillain-Barre syndrome within 6 weeks of receipt of influenza vaccine
Influenza

Contraindications / Precautions

• LAIV

• Contraindications
  - History of severe allergic reactions to any component of the vaccine, including egg protein, gelatin, and other components
  - In addition, ACIP recommends against use in the following:
    - Children aged < 2 years*
    - Adults aged ≥ 50 years*
    - Children 2-4 years with recurrent wheezing or asthma in the preceding 12 months*
    - Persons with asthma*
    - Persons with chronic medical conditions*
    - Persons with immunosuppression*
    - Persons in close contact with severely immunosuppressed patients who require a protected environment*
    - Pregnant women*

• Concomitant aspirin therapy in children and adolescents*

* These persons should receive IIV

Influenza

Contraindications / Precautions

• LAIV

• Precautions
  - Moderate to severe illness with or without fever
  - History of Guillain-Barre syndrome within 6 weeks of receipt of influenza vaccine

• Drug Interactions
  - Influenza antiviral agents
    - Do not administer vaccine until 48 hours after antiviral use is discontinued
    - Do not administer antiviral agents until 2 weeks after vaccine administration unless medically necessary

Testing Your Knowledge…

Which of the following antiviral agents has a drug interaction with the influenza vaccine and would require separation?

a) Acyclovir (Zovirax)
b) Oseltamivir (Tamiflu)
c) Ritonavir (Norvir)
d) Valacyclovir (Valtrex)
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**Influenza**

**Contraindications / Precautions**

- RIV
  - Contraindications
    - History of severe allergic reaction to any component of the vaccine
  - Precautions
    - Moderate to severe illness with or without fever
    - History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine

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**Seasonal Influenza Vaccines**

<table>
<thead>
<tr>
<th>Vaccine Name</th>
<th>Approved Age</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivated Influenza Vaccine (IIV4)</td>
<td>≥ 3 years</td>
<td>Quadrivalent</td>
</tr>
<tr>
<td>FluLaval</td>
<td>≥ 3 years</td>
<td>Quadrivalent</td>
</tr>
<tr>
<td>Fluarix</td>
<td>≥ 3 years</td>
<td>Quadrivalent</td>
</tr>
<tr>
<td>Fluzone</td>
<td>≥ 6 months</td>
<td>Quadrivalent</td>
</tr>
<tr>
<td>Fluzone Intradermal</td>
<td>18 to 64 years</td>
<td>Quadrivalent</td>
</tr>
<tr>
<td>Inactivated Influenza Vaccine (IIV3)</td>
<td>≥ 9 years</td>
<td>Jet injector</td>
</tr>
<tr>
<td>Afluria</td>
<td>≥ 9 years</td>
<td>Needle/syringe</td>
</tr>
<tr>
<td>Fluvirin</td>
<td>≥ 4 years</td>
<td></td>
</tr>
<tr>
<td>Fluzone (standard dose)</td>
<td>≥ 6 months</td>
<td></td>
</tr>
<tr>
<td>Fluzone High-Dose</td>
<td>≥ 65 years</td>
<td></td>
</tr>
<tr>
<td>Inactivated Influenza Vaccine Cell-Culture (ccIIV3)</td>
<td>≥ 18 years</td>
<td></td>
</tr>
<tr>
<td>Flucelvax</td>
<td>≥ 18 years</td>
<td></td>
</tr>
<tr>
<td>Recombinant influenza Vaccine (RIV3)</td>
<td>≥ 18 years</td>
<td></td>
</tr>
<tr>
<td>Flublok</td>
<td>≥ 18 years</td>
<td></td>
</tr>
<tr>
<td>Live Attenuated Influenza Vaccine (LAIV4)</td>
<td>2 to 49 years (healthy, not pregnant)</td>
<td>Quadrivalent</td>
</tr>
</tbody>
</table>

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**ACIP Votes Down Use of LAIV**

- June 22, 2016 ACIP Meeting
  - Poor or lower efficacy of LAIV for children 2 to 17 years from 2013-2016
    - 2015-2016 – vaccine effectiveness (VE) for LAIV was 3%
    - 2015-2016 – vaccine effectiveness (VE) for IIV was 63%
  - ACIP recommended to NOT use LAIV during the 2016-2017 influenza season
  - This recommendation must be reviewed and approved by the CDC Director

New Influenza Vaccine

Fluad, influenza vaccine adjuvanted

- Approved November 24, 2015
- First influenza vaccine approved containing an adjuvant (MF59C.1)
- Squalene based oil-water emulsion
- Trivalent inactivated influenza vaccine (IIV3)
- Indicated/approved for 65 years of age and older
- Efficacy study – Fluad induced antibody levels that were comparable to non-adjuvanted vaccine
- Safety – ADEs include injection site pain and tenderness, muscle aches, headache, fatigue

Recommended Influenza Vaccine Composition 2016-2017

- A/California/7/2009 (H1N1)pdm09-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus
- Additional strain for quadrivalent vaccines
- B/Phuket/3073/2013-like virus

Case 1
- MD, an 18 year old male, presents to his primary care provider for an annual well visit. He needs documentation of immunizations prior to entering college in the fall.
- What is the first question that you should ask MD about immunizations?

MD’s Immunization Record
- HepB – completed series
- RV – completed series
- DTaP – completed series
- Hib – completed series
- PCV7 x 4 – last given at 1 year old
- IPV – completed series
- Influenza x 10 – last given at 8 years old
- MMR x 2 – last given at 5 years old
- HepA – completed series
- MCV4 x 1 – last given at 12 years old
- Tdap x 1 – last given at 12 years old
- HPV x 2 – last given at 12 years old

Screening Questionnaire
1. Are you sick today? No
2. Does the child have allergies to medications, food, a vaccine component, or latex? No
3. Has the child had a serious reaction after receiving a vaccine in the past? No
4. As the child had a health problem with lung, heart, kidney or metabolic disease (e.g. diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? No
5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? N/A
6. If your child is a baby, have you ever been told he or she has had intussusception? N/A
7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? No
8. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? No
9. In the past 3 months, has the child taken medications that affect the immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn’s disease, or psoriasis; or had radiation treatments? No
10. In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? No
11. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? N/A
12. Has the child received vaccinations in the past 4 weeks? No

What vaccinations are recommended for MD?
Case 1 Summary

- Inactivated influenza vaccine (IIV3/IIV4) OR Live attenuated influenza vaccine (LAIV4)
- Meningococcal conjugate vaccine (MCV4)
- Human papillomavirus vaccine (HPV9)
- Meningococcal serogroup B vaccine

Case 2

AW is a 32 year old female with Type 1 diabetes who presents to the community pharmacy for a refill of her prenatal vitamins and insulin prescriptions. She is 32 weeks pregnant. She remembers her OB/GYN mentioned she should get a couple of vaccinations.

What is the first question that you should ask AW about immunizations?
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**AW's Immunization Record**
- Up-to-date at 11 to 12 year old well child visit
- No immunizations since

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**Screening Questionnaire**

<table>
<thead>
<tr>
<th>Screening Question</th>
<th>Response</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>3. Have you ever had a serious reaction after receiving a vaccination?</td>
<td>No</td>
</tr>
<tr>
<td>4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g. diabetes), anemia, or other blood disorder?</td>
<td>No</td>
</tr>
<tr>
<td>5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?</td>
<td>No</td>
</tr>
<tr>
<td>6. In the past 3 months, have you taken medications that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?</td>
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<td>7. Have you had a seizure or a brain or other nervous system problem?</td>
<td>No</td>
</tr>
<tr>
<td>8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?</td>
<td>No</td>
</tr>
<tr>
<td>9. For women: Are you pregnant or is there a chance you could become pregnant during the next month?</td>
<td>YES</td>
</tr>
<tr>
<td>10. Have you received any vaccinations in the past 4 weeks?</td>
<td>No</td>
</tr>
</tbody>
</table>

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**Schedule for Adults**
By Medical or Other Indication
Case 2 Summary
- Inactivated influenza vaccine (IIV3/IIV4)
- Tetanus-diphtheria-acellular pertussis vaccine (Tdap)
- Hepatitis B vaccine
- Pneumococcal polysaccharide vaccine (PPSV23)

Case 3
- NS, a 66 year old male, presents to the community pharmacy for his annual influenza vaccine.
- What is the first question that you should ask NS about immunizations?

NS’s Immunization Record
- Influenza – yearly x 10 years
- Unsure of childhood immunizations
• What vaccinations are recommended for NS?

### Screening Questionnaire

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</tr>
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<td>2. Do you have allergies to medications, food, a vaccine component, or latex?</td>
<td>YES</td>
</tr>
<tr>
<td>3. Have you ever had a serious reaction after receiving a vaccination?</td>
<td>No</td>
</tr>
<tr>
<td>4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g. diabetes), anemia, or other blood disorder?</td>
<td>No</td>
</tr>
<tr>
<td>5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?</td>
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<td>6. In the past 3 months, have you taken medications that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?</td>
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<td>7. Have you had a seizure or a brain or other nervous system problem?</td>
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### Schedule for Adults by Age

- Fluzone Package Insert
- Boostrix Package Insert
- Zostavax Package Insert
- Not listed in package insert (need to call manufacturer)
- Prevnar 13 Package Insert

### Latex Allergy
What do we do?
- Fluzone Package Insert
- Boostrix Package Insert
- Zostavax Package Insert
- Not listed in package insert (need to call manufacturer)
- Prevnar 13 Package Insert

The top cap and other parts of the Fluzone syringe are not made with natural rubber latex.
Case 3 Summary
- Inactivated influenza vaccine (IIV3/IIV4)
- Tetanus-diphtheria-acellular pertussis vaccine (Tdap)
- Zoster vaccine
- Pneumococcal conjugate vaccine (PCV13)
- One year later
  - Pneumococcal polysaccharide vaccine (PPSV23)

CPE Instructions
- There is no code associated with this activity.
  All participants were to have pre-registered on the CEI website.
  Once your credit has been claimed, the activity will move to your Completed Activities.