Immunization Update

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Associate Professor | UNE
Objectives

- Discuss the gap between current rates and Healthy People 2020 goals for vaccinations.
- Categorize each of the CDC recommended flu vaccines based upon live/inactivated, route, prep., and storage.
- Discuss the influenza vaccines for 2015 including the new quadrivalent and mammalian cell vaccines.
- Identify vaccine contraindications and recommend vaccines based upon age and medical history.
- Apply ACIP recommendations and FDA approved indications for the CDC recommended vaccines.
- Recognize federal and state laws that regulate vaccine administration.
Outline

• Background & Principles of Vaccination
• Regulations
• Influenza Vaccines
• Pneumococcal Vaccines
• HPV9 Vaccine
BACKGROUND & PRINCIPLES OF VACCINATION
2015 ACIP 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>22-26 years</th>
<th>27-49 years</th>
<th>50-59 years</th>
<th>60-64 years</th>
<th>≥ 65 years</th>
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</thead>
<tbody>
<tr>
<td>Influenza^2</td>
<td></td>
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<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap)^1,3</td>
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<tr>
<td>Varicella^4</td>
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<tr>
<td>Human papillomavirus (HPV) Female^5</td>
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<tr>
<td>Human papillomavirus (HPV) Male^5</td>
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<tr>
<td>Zoster^6</td>
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<tr>
<td>Measles, mumps, rubella (MMR)^27</td>
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<td>Pneumococcal 13-valent conjugate (PCV13)^5,8</td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23)^7</td>
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<td>Hepatitis B^11</td>
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<tr>
<td>Haemophilus influenzae type b (Hib)^22</td>
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</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program

www.cdc.gov/vaccines/schedules/hcp/adult.html
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>Immuno-compromising 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>Healthcare personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
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<tr>
<td>Tetanus, diphtheria, pertussis (Td/Tdap)</td>
<td>1 dose each pregnancy</td>
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<tr>
<td>Varicella</td>
<td></td>
<td>Contraindicated</td>
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<td></td>
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<tr>
<td>Human papillomavirus (HPV) Female</td>
<td>3 doses through age 26 yrs</td>
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<tr>
<td>Human papillomavirus (HPV) Male</td>
<td>3 doses through age 26 yrs</td>
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<tr>
<td>Zoster</td>
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<td>Contraindicated</td>
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<tr>
<td>Measles, mumps, rubella (MMR)</td>
<td></td>
<td>Contraindicated</td>
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<tr>
<td>Pneumococcal 13-valent conjugate (PCV13)</td>
<td>1 dose</td>
<td></td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23)</td>
<td>1 or 2 doses</td>
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<tr>
<td>Meningococcal</td>
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<tr>
<td>Hepatitis A</td>
<td></td>
<td>2 doses</td>
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<tr>
<td>Hepatitis B</td>
<td></td>
<td>3 doses</td>
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<tr>
<td>Haemophilus influenza type b (Hib)</td>
<td>post-HSCT recipients only</td>
<td></td>
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</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program

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

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

No recommendation

www.cdc.gov/vaccines/schedules/hcp/adult.html
FEDERAL AND STATE REGULATIONS
The Maine Experience
An Act Regarding the Administration of Vaccines by Pharmacists

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 32 MRSA §13831, sub-§1, as enacted by PL 2009, c. 308, §3, is amended to read:

1. Administration of influenza vaccines. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board may administer topically or by injection or by inhalation all forms of influenza vaccines, including intranasal influenza vaccines, to a person 97 years of age or older without a prescription.
# Maine Pharmacist-Administered Immunization Regulations

<table>
<thead>
<tr>
<th></th>
<th>No Rx Required</th>
<th>Rx Required&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Rx or Protocol</th>
<th>Not permitted</th>
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<tbody>
<tr>
<td><strong>Adult (≥18 years) with PCP&lt;sup&gt;b&lt;/sup&gt;</strong></td>
<td></td>
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</tr>
<tr>
<td>Influenza</td>
<td>✓ -RPh or Intern</td>
<td></td>
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<tr>
<td>Other Vaccines&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td>✓ -RPh or Intern</td>
<td></td>
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<tr>
<td><strong>Adult (≥18 years) without PCP</strong></td>
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</tr>
<tr>
<td>Influenza</td>
<td>✓ -RPh or Intern</td>
<td></td>
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</tr>
<tr>
<td>Other Vaccines&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td>✓ -RPh or Intern</td>
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<tr>
<td><strong>Child &lt; 18 years</strong></td>
<td></td>
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</tr>
<tr>
<td>Other Vaccines&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td><strong>Child 7-17 years</strong></td>
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<td></td>
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<td>✗</td>
</tr>
<tr>
<td>Influenza</td>
<td>✓ -RPh only</td>
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</tr>
<tr>
<td><strong>Child &lt;7 years</strong></td>
<td></td>
<td></td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>Influenza</td>
<td></td>
<td></td>
<td></td>
<td>✗</td>
</tr>
</tbody>
</table>

Intern administration permitted as indicated under direct supervision of licensed pharmacist

<sup>a</sup> Verbal/phone authorization acceptable

<sup>b</sup> Primary care physician or existing relationship with a nurse practitioner or an authorized practitioner in Maine

<sup>c</sup> All vaccines licensed by the US FDA recommended by the CDC ACIP
INFLUENZA VACCINES
Influenza Virus

- Influenza A viral structure
  - Viral genome covered by a protein shell (capsid) and a lipid bi-layer (envelope)\(^1\)
  - 2 main proteins on the envelope:\(^1,2\)
    - Hemagglutinin
    - Neuraminidase

Influenza Positive Tests Reported to CDC by Public Health Laboratories, National Summary, 2015-16 Season, week ending Nov 07, 2015
Reported by: U.S. WHO/NREVSS Collaborating Laboratories

- **Cumulative**
- **Most recent 3 weeks**

**Number of Influenza Positive Tests**
- A (H1) - 0
- A (Unable to Subtype) - 0
- A (H3) - 72
- A (H1N1)pdm09 - 16
- A (Subtyping not Performed) - 9
- B - 19
- H3N2v - 0
- B (Victoria Lineage) - 2
- B (Yamagata Lineage) - 1
- No Data
ACIP Recommendations 2015-16 Influenza Season

- For 2015–16, U.S.-licensed trivalent influenza vaccines will contain the A/California/7/2009 (H1N1)-like virus, an A/Switzerland/9715293/2013 (H3N2)-like virus, and a B/Phuket/3073/2013-like (Yamagata lineage) virus. This represents changes in the influenza A (H3N2) virus and the influenza B virus as compared with the 2014–15 season. Quadrivalent influenza vaccines will contain these vaccine viruses, and a B/Brisbane/60/2008-like (Victoria lineage) virus.

- All persons aged ≥6 months should receive influenza vaccine annually.

- Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV, or should avoid contact with such persons for 7 days after receipt, given the theoretical risk for transmission of the live attenuated vaccine virus.

- Persons who report having had reactions to egg involving such symptoms as angio-edema, respiratory distress, lightheadedness, or recurrent emesis; or who required medical attention must be excluded from receipt of any influenza vaccine containing egg protein. MMWR August 7, 2015 / 64(30):818-825
FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2015–16 influenza season

Has the child received ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1, 2015*

Yes

1 dose of 2015–16 influenza vaccine

No or don’t know

2 doses† of 2015–16 influenza vaccine

* The two doses need not have been received during the same season or consecutive seasons.
† Doses should be administered ≥4 weeks apart.
Egg Allergy

Recommendation

Can the patient eat lightly cooked egg (e.g., scrambled egg) without reaction?
- Yes: Administer vaccine per usual protocol
- No:
  - After eating eggs or egg-containing foods, does the patient experience ONLY hives?
    - Yes: Administer RIV3, if patient aged ≥18 years OR Administer IIV; observe for reaction for at least 30 minutes after vaccination.
    - No: After eating eggs or egg-containing foods, does the patient experience symptoms such as:
      - cardiovascular changes (e.g., hypotension)
      - respiratory distress (e.g., wheezing)
      - gastrointestinal symptoms (e.g., nausea or vomiting)
      - reaction requiring epinephrine
      - reaction requiring emergency medical attention.
        - Yes: Administer RIV3, if patient aged ≥18 years OR if RIV3 is not available, or if patient is aged <18 years, IIV should be administered by a physician with experience in the recognition and management of severe allergic conditions. Observe for reaction for at least 30 minutes after vaccination.
New Influenza Vaccines:

- **Fluarix®** (GlaxoSmithKline) – inactivated, quadrivalent vaccine
  - FDA approved December 2012
  - People ages 3 years and older
- **Fluzone®** (Sanofi Pasteur) – inactivated, quadrivalent vaccine.
  - FDA approved March 2013
  - People ages 6 months and older
- **Flumist®** Quadrivalent (MedImmune) – live, attenuated, quadrivalent vaccine
  - FDA approved March, 2012
  - People ages 2 through 49 years
- **Flucelvax®** (Novartis) – trivalent inactivated vaccine grown in mammalian cells.
  - FDA approved November, 2012
  - Adults 18 years and older
  - Doesn’t list “severe allergic reaction to egg protein” in the contraindications
- **Flublok®** (Protein Sciences Corp.) – inactivated, trivalent, recombinant vaccine.
  - FDA approved March 2013
  - People ages 18 years and older
  - Doesn’t list “severe allergic reaction to egg protein” in the contraindications
- **Fluzone Intradermal Quadrivalent** (Sanofi)-inactivated, quadrivalent vaccine
  - FDA approved January, 2015
  - Adults 18 to 64 years of age
# Age Indication for Influenza Vaccines: United States, 2015-16

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0.5-2 years</th>
<th>2 years</th>
<th>3 years</th>
<th>4-8 years</th>
<th>9-17 years</th>
<th>18-49 years</th>
<th>50-64 years</th>
<th>65+ years</th>
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<tbody>
<tr>
<td>Fluzone / Fluzone Quad</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
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<tr>
<td>Flumist Quad</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Fluarix Quad</td>
<td></td>
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<td>✓</td>
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<td>FluLaval Quad</td>
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<td>Afluria¹</td>
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<tr>
<td>Flublok²</td>
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<td>✓</td>
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<tr>
<td>Fluzone Intradermal Quad</td>
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<td>✓</td>
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<tr>
<td>Fluzone High-Dose</td>
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<td>✓</td>
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</table>

1. Age indication per package insert is ≥5 years; however the ACIP recommends ≥9 years.
2. FDA labeled age indication expanded in 2015 to 18 years and older (now including adults 65+).
Which of the following was the predominant flu strain of 2014-15?

1. Type B strain in trivalent vaccine
2. Type B strain not in trivalent vaccine
3. Type A H1N1 strain
4. Type A H3N2 strain
Inactivated
Influenza
Vaccine (IIV)

Quadrivalent

Fluarix®, Fluzone®, FluLaval®, Fluzone Intradermal®
New Influenza Vaccines:

- **Fluarix Quadrivalent® (GlaxoSmithKline)** – inactivated, quadrivalent vaccine which contains two type A and two type B strains
  - FDA approved December 2012
  - People ages 3 years and older

- **Fluzone Quadrivalent® (Sanofi Pasteur)** – inactivated, quadrivalent vaccine which contains two type A and two type B strains
  - FDA approved March 2013
  - People ages 6 months and older
Does/will your pharmacy stock quadrivalent vaccine this season?

1. Yes
2. No
3. Not applicable

33% 33% 33%
Quadrivalent Influenza Vaccines contain which of the following?

1. Four type A strains
2. Two type A strains, 1 type B, & 1 type C
3. Two type A strains & 2 type B strains
4. Four type B strains

25%
25%
25%
25%
Live Attenuated Influenza Vaccine (LAIV) Quadrivalent FluMist®
New Influenza Vaccines:

- **Flumist® Quadrivalent (MedImmune)**—live attenuated vaccine which contains two type A and two type B strains
  - FDA approved March, 2012
  - People ages 2 through 49 years
Live Attenuated Influenza Vaccine

- Indication
  - Healthy people 2 through 49 years of age

- Contraindications
  - Pregnant women
  - People who have long-term health problems with:
    - heart disease
    - kidney or liver disease
    - lung disease
    - metabolic disease, such as diabetes
    - asthma
    - anemia, and other blood disorders
  - Anyone with a weakened immune system
  - Severe egg allergy

I pick my nose!
Administration

- Flumist®: 0.1-mL dose in each nostril
- Intranasal
Does/will your pharmacy stock Flumist this season?

- Yes: 33%
- No: 33%
- Not applicable: 33%
Which of the following patients is a candidate for the live influenza vaccine?

1. 45 yo man with severe egg allergy
2. 27 yo healthy woman
3. 38 yo man with diabetes
4. 54 yo healthy man
5. 19 yo pregnant woman
Inactivated Influenza Vaccine (IIV) Trivalent Mammalian Flucelvax®
New Influenza Vaccines:

• Flucelvax® (Novartis)– trivalent inactivated vaccine grown in mammalian cells rather than chicken embryo cells.
  – FDA approved November, 2012
  – Adults 18 years and older
  – Doesn’t list “severe allergic reaction to egg protein” in the contraindications
Does/will your pharmacy stock Flucelvax this season?

- Yes: 33%
- No: 33%
- Not applicable: 33%
Inactivated, Trivalent Recombinant Vaccine
Flublok®
New Influenza Vaccines:

- **Flublok®** (Protein Sciences Corporation)– trivalent inactivated vaccine grown in insect cells rather than chicken embryo cells.
  - FDA approved November, 2013
  - Adults 18 years and older (new indication as of April 2015; previously 18-49 years).
  - Doesn’t list “severe allergic reaction to egg protein” in the contraindications*

*Flublok contains no egg proteins, antibiotics, or preservatives. The stoppers used for the single-dose vials are not made with natural rubber latex.*
Does/will your pharmacy stock Flublok this season?

- Yes: 33%
- No: 33%
- Not applicable: 33%
Select an influenza vaccine for a healthy 37-year-old woman with severe egg allergy.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Flublok</td>
<td>25%</td>
</tr>
<tr>
<td>Flumist</td>
<td>25%</td>
</tr>
<tr>
<td>Fluzone</td>
<td>25%</td>
</tr>
<tr>
<td>Fluarix</td>
<td>25%</td>
</tr>
</tbody>
</table>
High-Dose Inactivated Influenza Trivalent Vaccine (IIV) 
Fluzone HD®
Efficacy of High-Dose versus Standard-Dose Influenza Vaccine in Older Adults


Methods:
- Multicenter, randomized, double-blind controlled study
- HD vaccine (60 mcg of hemagglutinin per strain): N=15,991
- SD vaccine (15 mcg of hemagglutinin per strain): N=15,998
- Adults 65 years and older. Nursing home residents and immunocompromised persons were excluded.

DiazGranados_2014_NEJM

• How well does the study design limit bias?
• Who was enrolled in the study/who does the study apply to?
• What is the primary outcome and is the result statistically significant?
• Is the result clinically significant? What is the benefit/risk?
Occurrence of laboratory-confirmed influenza following administration of HD and SD influenza vaccines

Efficacy of HD Vaccine vs. Standard Dose against Laboratory Confirmed Influenza of Any Type

• Number (%) of cases
  – IV3-HD: 228/15,990 (1.4%)
  – IV3-SD: 301/15,993 (1.9%)

• Relative Efficacy (95% CI)
  – 24.2% (9.7% – 36.5%)

• Absolute Efficacy
  – 0.5%

• Number Needed to Treat
  – 200
Which of the following statements is FALSE when comparing the efficacy of Fluzone HD to Fluzone in adults 65 years or older?

1. The relative efficacy of Fluzone HD is $24\% >$ than Fluzone
2. The absolute efficacy of Fluzone HD is $0.5\% >$ than Fluzone
3. These results apply to nursing home patients
4. The NNT is 200 to avoid one additional case of influenza
Does/will your pharmacy stock Fluzone HD this season?

<table>
<thead>
<tr>
<th></th>
<th>33%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Yes</td>
</tr>
<tr>
<td>2.</td>
<td>No</td>
</tr>
<tr>
<td>3.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Intradermal Quadrivalent Inactivated Influenza Vaccine (IIV) Fluzone Intradermal®
Intradermal Influenza Vaccine

• Indication
  – Persons 18 through 64 years of age

• Contraindications
  – Severe egg allergy
Intradermal vs Traditional IM needle Length

Shorter needle length (1.5mm Intanza vs 16mm IM)

Shorter needle length (1.5mm Intanza vs 16mm IM vs 25mm IM needles all available in Australia)
30 Gauge Needle and Less Volume

Smaller, finer needle gauge (30 gauge Intanza vs 25 gauge IM)

0.5ml Intramuscular
0.1ml Intradermal

Less volume (0.1mL Intanza vs 0.5mL IM)
Intradermal Injection Technique

1. Remove needle cap
2. Hold microinjection system between thumb and middle finger
   ❑ Do not place fingers on the windows
3. Insert needle rapidly perpendicular to the skin
4. Inject using the index finger
5. Remove needle from the skin and activate the needle shield by pushing firmly on the plunger
Does/will your pharmacy stock Fluzone Intradermal this season?

33%  

33%  

33%
Which side effect is more common with the intradermal influenza vaccine than the IM influenza vaccine?

0%  1. Injection site pain
0%  2. Headache
0%  3. Fever
0%  4. Injection site swelling
0%  5. Malaise
Influenza Vaccines: Summary
# Age Indication for Influenza Vaccines: United States, 2015-16

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0.5-2 years</th>
<th>2 years</th>
<th>3 years</th>
<th>4-8 years</th>
<th>9-17 years</th>
<th>18-49 years</th>
<th>50-64 years</th>
<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone / Fluzone Quad</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Flumist Quad</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fluarix Quad</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Flulaval Quad</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Fluvirin</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Afluria¹</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Flucelvax</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Flublok²</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fluzone Intradermal Quad³</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone High-Dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

1. Age indication per package insert is ≥5 years; however the ACIP recommends ≥9 years.
2. FDA labeled age indication expanded in 2015 to 18 years and older (now including adults 65+).
3. Reformulated to Quadrivalent in 2015.
## Characteristics of Influenza Vaccines: United States, 2015-16

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Live</th>
<th>Mercury</th>
<th>Egg Protein</th>
<th>Latex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone / Fluzone Quad</td>
<td>✓</td>
<td>✓ 1</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Flumist Quad</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Fluarix Quad</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>FluLaval Quad</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Fluvirin</td>
<td>✓ 1</td>
<td></td>
<td>✓</td>
<td>✓ 3</td>
</tr>
<tr>
<td>Afluria</td>
<td>✓ 1</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Flucelvax</td>
<td></td>
<td>✓ 2</td>
<td>✓ 3</td>
<td></td>
</tr>
<tr>
<td>Flublok</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone Intradermal Quad</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone High-Dose</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

1. Multi-dose vials contain mercury. Single-dose prefilled syringes are mercury-free.
2. Estimated to contain <50 femtograms (5x10^-8 mcg) of total egg protein per 0.5 ml dose.
3. Syringe tip may contain natural rubber latex.
## Route of Admin. for Influenza Vaccines: United States, 2015-16

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Young Children*</th>
<th>Older Children</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone / Fluzone Quad</td>
<td>IM Thigh</td>
<td>IM Deltoid</td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>Flumist Quad</td>
<td>Intranasal</td>
<td>Intranasal</td>
<td>Intranasal</td>
</tr>
<tr>
<td>Fluarix Quad</td>
<td>IM Thigh</td>
<td>IM Deltoid</td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>FluLaval Quad</td>
<td>IM Thigh</td>
<td>IM Deltoid</td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>Fluvirin</td>
<td>IM Thigh</td>
<td>IM Deltoid</td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>Afluria</td>
<td></td>
<td>IM Deltoid</td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>Flucelvax</td>
<td></td>
<td></td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>Flublok</td>
<td></td>
<td></td>
<td>IM Deltoid</td>
</tr>
<tr>
<td>Fluzone Intradermal Quad</td>
<td></td>
<td></td>
<td><strong>ID</strong> Deltoid</td>
</tr>
<tr>
<td>Fluzone High-Dose</td>
<td></td>
<td></td>
<td>IM Deltoid</td>
</tr>
</tbody>
</table>

*Generally, less than 7 years old.*
Which of the following influenza vaccine(s) is/are appropriate for a healthy 16-year-old boy.

1. Fluzone
2. Fluzone ID
3. Fluzone HD
4. Flucelvax
5. 1 and 2
Which of the following influenza vaccines is NOT indicated for a 72-year-old woman?

1. Inactivated trivalent IM vaccine
2. Inactivated quadrivalent vaccine
3. Inactivated high dose vaccine
4. Inactivated trivalent intradermal vaccine

25%  25%  25%  25%
Pneumococcal Vaccine
PPSV23 / Pneumovax®
PCV13 / Pnevnar®
US Adult Vaccination Rates Are Low

Estimated % of US Adults Who Have Received Pneumococcal Vaccine

- **All high-risk** (2011)³, (2011)³: 20.1%

**High-Risk Adults Aged <65 Years**

- **All adults** (2008)²: 60%
- **All adults** (2011)³: 62.3%

**Adults Aged ≥65 Years**

- **90% Goal¹,a**

¹Healthy People 2020 goal. ²Adults aged 18–64 years. ³Adults aged 19–64 years.

---

Background

- *Streptococcus pneumoniae*
  - 90 serotypes identified
  - The 10 most common serotypes are estimated to account for about 62% of invasive disease worldwide
  - Up to 36% of adult CAP
  - Up to 50% of HAP
  - 13-19% of all cases of meningitis

Pneumococcal Vaccines

- Pneumovax 23® (PPSV23, pneumococcal polysaccharide vaccine)
- Prevnar 13® (PCV13, pneumococcal conjugate vaccine)
Serotypes Contained in PPSV23 & PCV13

PPSV23 contains 23 serotypes, of which 11 are unique

PCV13 contains 13 serotypes, of which 1 is unique

- Pink: Serotypes contained in both vaccines
- Orange: Serotypes unique to PPSV23
- Gray: Serotype unique to PCV13
# PPSV23 (Pneumovax®)

<table>
<thead>
<tr>
<th>Age</th>
<th>Who receives the vaccine?</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥65 years old</td>
<td>• Vaccination history unclear or never received vaccine before&lt;br&gt;• Revaccinate: If patient received vaccine before the age of 65 and it has been ≥ 5 years since administration</td>
</tr>
<tr>
<td>2-64 years old</td>
<td>• Chronic cardiovascular disease (CHF, cardiomyopathies)&lt;br&gt;• Chronic pulmonary disease (COPD)&lt;br&gt;• Diabetes mellitus&lt;br&gt;• Alcoholism&lt;br&gt;• Chronic liver disease&lt;br&gt;• Cerebrospinal fluid leaks&lt;br&gt;Re-vaccination after 5 years if: (see figure 1 on next slide)&lt;br&gt;• functional or anatomic asplenia&lt;br&gt;• Immunocompromising conditions&lt;br&gt;• Chronic kidney disease</td>
</tr>
<tr>
<td>19-64 years old</td>
<td>• Cigarette smokers&lt;br&gt;• Asthma</td>
</tr>
</tbody>
</table>

ACIP Recommendations on Pneumococcal Vaccinations in Adults
Pneumococcal vaccine-naïve persons aged ≥ 65 years

*minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks; PPSV23 can be given later than 6-12 months after PCV13 if this window is missed.
Persons who previously received PPSV23 at age ≥ 65 years

*minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks; PPSV23 can be given later than 6-12 months after PCV13 if this window is missed.
Persons who previously received PPSV23 before age 65 years who are now aged ≥ 65 years
Methods:

- Multicenter, randomized, double-blind controlled study
- PCV13 Vaccine: N=42,240
- Placebo: N=42,256
- Adults 65 years and older. Nursing home residents and immunocompromised persons were excluded.
How well does the study design limit bias?
Who was enrolled in the study/who does the study apply to?
What is the primary outcome and is the result statistically significant?
Is the result clinically significant? What is the benefit/risk?
Analysis of the Cumulative Episodes of Vaccine-Type CAP in the Per-Protocol Population

Years since Vaccination

Cumulative No. of Episodes

Placebo

PCV13

Efficacy of PCV13 vs Placebo: First episode of confirmed CAP (Per Protocol)

- Number (%) of cases
  - PCV13: 49/42,240 (x.x%)
  - Placebo: 90/42,256 (x.x%)

- Relative Efficacy (95% CI)
  - 45.6% (21.8% – 62.5%), p<0.001

- Absolute Efficacy

- Number Needed to Treat
A 67-year-old woman has a history of type 2 diabetes. No prior pneumonia vaccination. What pneumonia vaccine(s) is/are recommended?

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumovax only</td>
<td>25%</td>
</tr>
<tr>
<td>Prevnar only</td>
<td>25%</td>
</tr>
<tr>
<td>Both; Pneumovax prior to Prevnar</td>
<td>25%</td>
</tr>
<tr>
<td>Both; Prevnar prior to Pneumovax</td>
<td>25%</td>
</tr>
</tbody>
</table>
QUESTIONS AND DISCUSSION

UNE College of Pharmacy
HUMAN PAPILLOMA VIRUS

GARDASIL® (HPV4) – TYPES 6,11,16,18

GARDASIL9® (HPV9) – TYPES 6,11,16,18,31,33,45,52,58

CERVARIX® (HPV2) – TYPES 16,18
HPV Overview

- Nonenveloped, double-stranded DNA virus\(^1\); necessary cause of cervical cancer.\(^2\)

- More than 100 types of HPV viruses identified; 30 to 40 infect the anogenital tract.\(^3,4\)
  - HPV 16 and 18 account for ~70% of cervical cancers worldwide.\(^5\)
  - HPV 16 and 18 are also associated with precancerous lesions.\(^6\)

HPV is Widespread

- ~8 in 10 people will be infected with HPV in their lifetime.\(^1,\text{a}\)
  - ~20 million people in the US are currently infected with HPV.\(^1,\text{2}\)
  - ~17,000 new HPV infections occur every day in the US.\(^2\)

- Although most HPV infections clear on their own, persistence of certain HPV types can lead to clinically significant diseases.\(^2\)

- For HPV-associated cervical disease, it cannot be reliably predicted which patients with infection or abnormal smears will progress to clinically significant disease versus spontaneously regress.\(^3,\text{4}\)

\(\text{a}\)This rate represents more than 30 HPV types, not just Types 6, 11, 16, and 18.

HPV = human papillomavirus.

Type Attribution by Cancer Site, US

- HPV 16/18
- HPV 31/33/45/52/58
- Other HPV
- HPV Negative

Percent

Cancer Site:
- Cervical
- In Situ Cervical
- Vulvar
- Vaginal
- Anal
- Penile
- Oropharyngeal

Saraiya et al, February 2014, ACIP
Natural History of High-Risk HPV Infection and Potential Progression to Cervical Cancer

CIN = cervical intraepithelial neoplasia.

HPV Is Associated With Many Anogenital Conditions

HPV = human papillomavirus.

Estimated Annual Burden of HPV-Related Diagnoses in the United States, 2011

WOMEN
~12,700 new cases of cervical cancer¹
~4,300 new cases of vulvar cancer¹,a
~2,600 new cases of vaginal cancer¹,a

MEN and WOMEN
~5,800 new cases of anal cancer¹,a

WOMEN
~330,000 new cases of high-grade cervical dysplasia²

WOMEN
~1.4 million new cases of low-grade cervical dysplasia²,a

MEN and WOMEN
~1 million new cases of genital warts³

Estimated new HPV infections per year (incidence): ~6.2 million⁴
Estimated active HPV infections (prevalence): ~20 million⁴

¹Not all cases are related to HPV infection.
HPV = human papillomavirus.
FDA News Release

FDA approves Gardasil 9 for prevention of certain cancers caused by five additional types of HPV

For Immediate Release

December 10, 2014

Release

The U.S. Food and Drug Administration today approved Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) for the prevention of certain diseases caused by nine types of Human Papillomavirus (HPV). Covering nine HPV types, five more HPV types than Gardasil (previously approved by the FDA), Gardasil 9 has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal and anal cancers.

Gardasil 9 is a vaccine approved for use in females ages 9 through 26 and males ages 9 through 15. It is approved for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, and for the
## HPV vaccine options

<table>
<thead>
<tr>
<th>Vaccine ▼</th>
<th>Who is it for?</th>
<th>How many doses?</th>
<th>What infections does it prevent?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervarix</td>
<td>Girls 9 to 26 years of age.</td>
<td>3</td>
<td>HPV types 16 and 18 (which cause cancer).</td>
</tr>
<tr>
<td>Gardasil</td>
<td>Girls and boys 9 to 26 years of age.</td>
<td>3</td>
<td>HPV types 6, 11 (which cause genital warts), and HPV 16 and 18 (which cause cancer).</td>
</tr>
<tr>
<td>Gardasil 9</td>
<td>Girls ages 9 to 26; boys ages 9 to 15.</td>
<td>3</td>
<td>HPV types 16, 18, 31, 33, 45, 52 and 58 (which cause cancer), and HPV types 6 or 11 (which cause warts).</td>
</tr>
</tbody>
</table>

Patient Information about GARDASIL®9 (pronounced “gard-Ah-sill nihn”)  
(Human Papillomavirus 9-valent Vaccine, Recombinant)

Read this information with care before getting GARDASIL®9. You or your child (the person getting GARDASIL 9) will need 3 doses of the vaccine. It is important to read this information before getting each dose. This information does not take the place of talking with your health care professional about GARDASIL 9.

What is GARDASIL 9? 
GARDASIL 9 is a vaccine (injection/shot) given to girls and women 9 through 26 years of age and to boys 9 through 15 years of age to help protect against diseases caused by some types of Human Papillomavirus (HPV).

What diseases can GARDASIL 9 help protect against? 
In girls and women 9 through 26 years of age, GARDASIL 9 helps protect against:
- Cervical cancer
- Vulvar and vaginal cancers
- Anal cancer
- Precancerous cervical, vulvar, vaginal and anal lesions
- Genital warts

In boys 9 through 15 years of age, GARDASIL 9 helps protect against:
- Anal cancer
- Precancerous anal lesions
- Genital warts

These diseases have many causes. Most of the time, these diseases are caused by nine types of HPV: HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL 9 only protects against diseases caused by these nine types of HPV.

People cannot get HPV or any of these diseases from GARDASIL 9.

Can I get GARDASIL 9 if I have already gotten GARDASIL? 
If you have already gotten GARDASIL, talk to your health care professional to see if GARDASIL 9 is right for you.
The Advisory Committee on Immunization Practices (ACIP) recommends routine HPV vaccination at age 11 or 12 years. The vaccination series can be started beginning at age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated. ACIP recommends vaccination of men who have sex with men and immunocompromised persons through age 26 years if not vaccinated.
2vHPV, 4vHPV, and 9vHPV all protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States (1,12). 9vHPV targets five additional cancer causing types, which account for about 15% of cervical cancers (12). 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts.
HPV Vaccination Schedule

- Routine schedule is 0, 2, 6 months
- Third dose should follow the first dose by at least 24 weeks
- An accelerated schedule using minimum intervals is not recommended
- Series does not need to be restarted if the schedule is interrupted
HPV Vaccination During Pregnancy

- Initiation of the vaccine series should be delayed until after completion of pregnancy.
- If a woman is found to be pregnant after initiating the vaccination series, remaining doses should be delayed until after the pregnancy.
- If a vaccine dose has been administered during pregnancy, there is no indication for intervention.
- Women vaccinated during pregnancy should be reported to the respective manufacturer.

*MMWR 2010;59(No. 20):626*
Administration

- Gardasil®/Cervarix®
- IM - deltoid
- 1 inch, 25 gauge needle
The mother of a 12-year-old boy requests the HPV vaccination. Select the correct vaccine and series.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Series</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gardasil®</td>
<td>3 dose series</td>
</tr>
<tr>
<td>Cervarix®</td>
<td>3 dose series</td>
</tr>
<tr>
<td>Gardasil®</td>
<td>2 dose series</td>
</tr>
<tr>
<td>Cervarix®</td>
<td>2 dose series</td>
</tr>
</tbody>
</table>

25% 25% 25% 25%