2013-2014 Influenza Season

Influenza Vaccines

August 28, 2013

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Overview

- Influenza summary for 2012-2013
- Vaccine virus strains for 2013-2014
- Influenza vaccines available for 2013-2014
  - NEW Quadrivalent vaccines
  - NEW cell-based and recombinant trivalent vaccines
- Influenza vaccine recommendations
- Influenza vaccines in RPMS
- Resources
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2012-13 and Selected Previous Seasons
Pneumonia and Influenza Mortality for 122 U.S. Cities
Week Ending August 17, 2013
2012-2013 Influenza Season Recap

• Relatively early season
  – Influenza-like-illness peaked in December
• More severe than previous season
• Predominantly H3N2
• Higher hospitalization and mortality rates among the elderly
• 158 pediatric deaths
  – Higher than the 2 previous seasons
  – 2009-2010 Pandemic – 282 deaths
IHS INFLUENZA VACCINE COVERAGE FOR 2012-2013
IHS Influenza Vaccine Coverage
1 dose, All Ages (≥ 6 months)

IHS Influenza Awareness System (IIAS) vs. Quarterly Immunization Package reports from RPMS
IHS Influenza Vaccine Coverage
2012 - 2013

IIAS – IHS Influenza Awareness System; RPMS – RPMS Quarterly Immunization Report
IHS Healthcare Personnel Influenza Vaccination Coverage

IHS Influenza Vaccine Coverage reports available at: www.ihs.gov/flu
INFLUENZA VACCINES FOR 2013-2014
Vaccine virus strains for 2013-2014

• The 2013-2014 trivalent influenza vaccine is made from the following three viruses:
  – A/California/7/2009 (H1N1)pdm09-like virus
  – A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011
  – B/Massachusetts/2/2012-like virus

• For quadrivalent influenza vaccines, a second B strain is added to the 3 strains listed above
  – B/Brisbane/60/2008-like virus

Influenza B

- Less antigenic diversity than influenza A
- Prior to 1980: B/Yamagata was major circulating lineage
- 1980: B/Victoria emerged
- Both lineages with drift variants circulate globally, generally with one predominating during any given season
- More difficult to predict than influenza A: mismatch between vaccine and circulating strains 6 of 12 seasons, 2001-2012
- 2012: WHO recommends quadrivalent vaccines containing both B lineages

Dolin R. *J Infect Dis* 2013; 208:539-40
Flu vaccines – New Nomenclature

- Trivalent Inactivated Influenza Vaccine
  - Formerly TIV, now IIV3
- Quadrivalent Inactivated Influenza Vaccine
  - Formerly QIV, now IIV4
- Live Attenuated Influenza Vaccine, Quadrivalent
  - LAIV4
- Recombinant Inactivated Influenza Vaccine, Trivalent
  - RIV3
- Cell Culture Inactivated Influenza Vaccine, Trivalent
  - cclIIV3
# Flu Vaccines available for 2013-2014

## TABLE 1. Influenza Vaccines — United States, 2013–14 influenza season*

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Trade name</th>
<th>Manufacturer</th>
<th>Age Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivated Influenza Vaccine, Trivalent† (IIV3), Standard Dose</td>
<td>Afluria®</td>
<td>CSL Limited</td>
<td>≥ 9 yrs</td>
</tr>
<tr>
<td></td>
<td>Fluarix®</td>
<td>GlaxoSmithKline</td>
<td>≥ 3 yrs</td>
</tr>
<tr>
<td></td>
<td>Flucelvax®§§§</td>
<td>Novartis Vaccines</td>
<td>≥ 18 yrs</td>
</tr>
<tr>
<td></td>
<td>FluLaval®</td>
<td>ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)</td>
<td>≥ 3 yrs</td>
</tr>
<tr>
<td></td>
<td>Fluvirin®</td>
<td>Novartis Vaccines</td>
<td>≥ 4 yrs</td>
</tr>
<tr>
<td></td>
<td>Fluzone®</td>
<td>Sanofi Pasteur</td>
<td>≥ 6 months</td>
</tr>
<tr>
<td></td>
<td>Fluzone® Intradermal§</td>
<td>Sanofi Pasteur</td>
<td>18 yrs through 64 yrs</td>
</tr>
<tr>
<td>Inactivated Influenza Vaccine, Trivalent† (IIV3), High Dose</td>
<td>Fluzone® High-Dose**</td>
<td>Sanofi Pasteur</td>
<td>≥ 65 yrs</td>
</tr>
<tr>
<td>Inactivated Influenza Vaccine, Quadrivalent† (IIV4), Standard Dose</td>
<td>Fluarix® Quadrivalent</td>
<td>GlaxoSmithKline</td>
<td>≥ 3 yrs</td>
</tr>
<tr>
<td></td>
<td>Fluzone® Quadrivalent</td>
<td>Sanofi Pasteur</td>
<td>≥ 6 months</td>
</tr>
<tr>
<td></td>
<td>FluLaval® Quadrivalent</td>
<td>GlaxoSmithKline</td>
<td>≥ 3 yrs</td>
</tr>
<tr>
<td>Recombinant Influenza Vaccine, Trivalent+++ (RIV3)</td>
<td>FluBlok®</td>
<td>Protein Sciences</td>
<td>18 yrs through 49 yrs</td>
</tr>
<tr>
<td>Live-attenuated Influenza Vaccine, Quadrivalent+++ (LAIV4)</td>
<td>FluMist® Quadrivalent+++</td>
<td>MedImmune</td>
<td>2 yrs through 49 yrs</td>
</tr>
</tbody>
</table>

Quadrivalent Vaccines

**Inactivated Influenza Vaccine quadrivalent (IIV4)**
- Fluarix® Quadrivalent (GlaxoSmithKline)
  - Age indication: ≥ 3 years
- FluLaval® Quadrivalent (GlaxoSmithKline)
  - Age indication: ≥ 3 years
- Fluzone® Quadrivalent (Sanofi Pasteur)
  - Age indication: ≥ 6 months
- All three vaccines are also available as trivalent vaccines

**Live Attenuated Influenza Vaccine Quadrivalent (LAIV4)**
- FluMist® Quadrivalent (Medimmune)
  - Age indication: 2 – 49 years
  - NOTE: ALL FluMist® will be quadrivalent. There will be no trivalent FluMist® available for the 2013-2014 season.
New trivalent Inactivated vaccines using alternative technologies

- **FluBlok** - Recombinant Influenza Vaccine, Trivalent\(^{+++}\) (RIV3) - Protein Sciences
  - 100% egg-free
  - Hemagglutinin proteins produced in an insect cell line
  - Age indication: 18-49 years old

- **Flucelvax** - Cell Culture Influenza Vaccine, Trivalent (cclIV3) – Novartis
  - Although not egg-based, traces of egg protein may remain, so is technically not 100% egg-free
  - “subunit” flu vaccine grown on MDCK cell line
  - Age indication: 18 years and older

http://www.flublok.com/ ; http://flucelvax.com/
Influenza Vaccine: Does It Work?

- Influenza Vaccine Effectiveness Network
- Case–control study during the 2012-13 season comparing vaccination histories between
  - 1,115 subjects with ARI documented to be influenza by rRT-PCR
  - 1,582 influenza test-negative controls
- Sites:
  - Seattle, WA (Group Health)
  - Marshfield, WI (Marshfield Clinic)
  - Ann Arbor and Detroit, MI (Univ of Michigan and Henry Ford Health System)
  - Pittsburgh, PA (University of Pittsburgh Medical Center)
  - Temple, TX (Scott and White Healthcare)

*MMWR* 2013; 62:119-123
### Influenza Vaccine Effectiveness Network, 2012-13, 2,697 Patients with ARI

The table below shows the vaccine effectiveness for different age groups and influenza subtypes.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Influenza + % Vaccinated</th>
<th>Influenza – % Vaccinated</th>
<th>Vaccine Effectiveness (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>33%</td>
<td>50%</td>
<td>56% (47%-63%)</td>
</tr>
<tr>
<td>6 mon-17 yrs</td>
<td>26%</td>
<td>49%</td>
<td>64% (51%-73%)</td>
</tr>
<tr>
<td>18 yrs-49 yrs</td>
<td>28%</td>
<td>42%</td>
<td>52% (38%-79%)</td>
</tr>
<tr>
<td>50 yrs-64 yrs</td>
<td>36%</td>
<td>58%</td>
<td>63% (43%-76%)</td>
</tr>
<tr>
<td>≥65 yrs</td>
<td>69%</td>
<td>72%</td>
<td>27% (-31%-59%)</td>
</tr>
<tr>
<td>Influenza A-H3N2</td>
<td>39%</td>
<td>50%</td>
<td>47% (35%-58%)</td>
</tr>
<tr>
<td>Influenza B</td>
<td>25%</td>
<td>47%</td>
<td>67% (51%-78%)</td>
</tr>
</tbody>
</table>

*MMWR 2013; 62:119-123*
Influenza Vaccine: Does It Work?

• Risk of medically attended influenza and fetal death among 117,347 pregnant women in Norway during 2009 pandemic
  – 54% vaccinated during 2\textsuperscript{nd} or 3\textsuperscript{rd} trimester
  – Vaccine effectiveness 70% (95% CI 66% to 75%)
  – Hazard ratio of fetal loss:
    • Vaccination: 0.88 (95% CI 0.66 to 1.17)
    • Influenza: 1.91 (95% CI 1.07 to 3.41)

• Benefits of vaccinating pregnant women
  – Less influenza illness and risk of death
  – Less fetal loss due to influenza
  – Some immunity during first 6 months of life

2013-2014 ACIP Flu Recommendations

• Routine annual influenza vaccination is recommended for all persons aged 6 months and older
  • Criteria for children < 9 yrs requiring 2 doses are the same as the 2012-2013 season
• ACIP expresses no preference for any one vaccine over another for persons for whom more than one type of vaccine is appropriate and available. e.g., no preference for
  • LAIV vs. IIV
  • Regular dose IIV3 vs. high-dose IIV3
  • Intramuscular IIV3 vs. intradermal IIV3
  • Quadrivalent vs. Trivalent vaccines (IIV4 vs. IIV3)
  • Cell culture/recombinant vs. egg-based
• Individuals living or caring for severely immuno-compromised (e.g. those living in a protective environment) should not receive LAIV
• Pregnant women should not receive LAIV
• Individuals with anaphylactic egg allergy should receive RIV3 if appropriate, or referred to a physician with experience managing allergic conditions for vaccination

Groups at Higher Risk for Influenza Complications

- Persons <2 or ≥65 years of age;
- Persons with the following conditions:
  - chronic pulmonary (including asthma),
  - cardiovascular (except hypertension),
  - renal, hepatic, hematological (including sickle cell) disease,
  - neurological, neuromuscular, or metabolic disorders (including diabetes mellitus);
- Immunosuppression, including that caused by medications or by HIV infection;
- Women who are pregnant or post-partum (2 weeks)
- Persons younger than 19 years of age who are receiving long-term aspirin therapy;
- American Indians and Alaska Natives;
- Persons who are morbidly obese (body-mass index ≥40);
- Residents of nursing homes and other chronic-care facilities.
Expanded dose algorithm for 6 months through 8 year olds

• One dose needed in 2013-14 if child received:
  – ≥ 2 seasonal Flu doses after 7/1/2010
  – ≥ 2 seasonal Flu doses before 7/1/2010 plus 1 dose of H1N1
  – ≥ 1 seasonal Flu dose before 7/1/2010 plus ≥ 1 dose since 7/1/2010

• Otherwise, children 6 months to <9 years need 2 doses at least 4 weeks apart
Recommendations for persons who have or report egg allergies

Can the person 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 person experience ONLY hives?

Yes → Administer RIV3, if patient aged 18 through 49 yrs.: OR

Administer IIV

Observe for reaction for at least 30 minutes following vaccination

No → After eating eggs or egg-containing foods, does the individual experience other symptoms such as:

- Cardiovascular changes (e.g., hypotension)
- Respiratory distress (e.g., wheezing)
- Gastrointestinal (e.g., nausea/vomiting)
- Reaction requiring epinephrine
- Reaction requiring emergency medical attention

Yes → Administer RIV3, if patient aged 18 through 49 yrs.: OR

Refer to a physician with expertise in management of allergic conditions for further evaluation

IIV=Inactivated Influenza Vaccine; RIV3=Recombinant Influenza Vaccine, Trivalent

*Individuals with egg allergy may tolerate egg in baked products (e.g., bread, cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (2).

† For individuals who have no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination. Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.
DOCUMENTING INFLUENZA VACCINES IN RPMS
# Influenza Vaccines in RPMS Version 8.5*5

<table>
<thead>
<tr>
<th>CVX Code</th>
<th>Full vaccine name (CDC abbreviation)</th>
<th>RPMS Short Name</th>
<th>Brand</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trivalent Inactivated Vaccines (IIV3)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>141</td>
<td>Influenza, seasonal, injectable, trivalent</td>
<td>FLU-IIV3</td>
<td>Afluria®, multi-dose vial</td>
<td>CSL Limited</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>FluLaval®, multi-dose vial</td>
<td>ID Biomedical Corp.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluvirin®, multi-dose vial</td>
<td>Novartis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluzone®, multi-dose vial</td>
<td>Sanofi Pasteur</td>
</tr>
<tr>
<td>140</td>
<td>Influenza, seasonal, injectable, preservative free, trivalent</td>
<td>FLU-IIV3pf</td>
<td>Afluria®, single dose syringe</td>
<td>CSL Limited</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluvarix®, single dose syringe</td>
<td>GSK</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluvirin®, single dose syringe</td>
<td>Novartis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluzone®, single dose syringe, single dose vial</td>
<td>Sanofi Pasteur</td>
</tr>
<tr>
<td>144</td>
<td>Seasonal influenza, intradermal, preservative free, trivalent</td>
<td>FLU-DERMAL</td>
<td>Fluzone® Intradermal</td>
<td>Sanofi Pasteur</td>
</tr>
<tr>
<td>135</td>
<td>Influenza, high dose seasonal, preservative-free</td>
<td>FLU-HIGH</td>
<td>Fluzone® High Dose</td>
<td>Sanofi Pasteur</td>
</tr>
<tr>
<td>155</td>
<td>Seasonal, trivalent, recombinant, injectable influenza vaccine, preservative free (RIV)</td>
<td>FLU-RIV3</td>
<td>FluBlok®</td>
<td>Protein Sciences</td>
</tr>
<tr>
<td>153</td>
<td>Influenza, injectable, Madin Darby Canine Kidney, preservative free (cell culture) (ccIIV3)</td>
<td>FLU-ccIIV3</td>
<td>Flucelvax®</td>
<td>Novartis</td>
</tr>
<tr>
<td><strong>Quadrivalent Inactivated Vaccines (IIV4)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>150</td>
<td>Influenza, injectable, quadrivalent, preservative free</td>
<td>FLU-IIV4pf</td>
<td>Fluvarix® Quadrivalent, single dose syringe</td>
<td>GSK</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fluzone® Quadrivalent, single dose syringe and single dose vial</td>
<td>Sanofi Pasteur</td>
</tr>
<tr>
<td>158</td>
<td>Influenza, injectable, quadrivalent</td>
<td>FLU-IIV4</td>
<td>FluLaval® Quadrivalent, multi dose vial</td>
<td>GSK</td>
</tr>
<tr>
<td><strong>Quadrivalent Live Attenuated Virus Vaccines (LAIV4)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>149</td>
<td>Influenza, live, intranasal, quadrivalent (LAIV4)</td>
<td>FLU-LAIV4</td>
<td>FluMist®</td>
<td>MedImmune</td>
</tr>
<tr>
<td><strong>Codes that should ONLY be used to record vaccines given elsewhere, if formulation is unknown</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>88</td>
<td>Influenza virus vaccine, unspecified formulation</td>
<td>FLU-NOS</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td><strong>Codes that should not be used this influenza season - Inactivate them in your vaccine table</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Influenza virus vaccine, split virus (incl. purified surface antigen)-retired CODE</td>
<td>FLU-TIVhx</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>16</td>
<td>Influenza virus vaccine, whole virus</td>
<td>FLU-WHOLE</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>111</td>
<td>Influenza virus vaccine, live, attenuated, for intranasal use, trivalent (LAIV3)</td>
<td>FLU-LAIV3</td>
<td>FluMist®</td>
<td>MedImmune</td>
</tr>
<tr>
<td>151</td>
<td>Influenza nasal, unspecified formulation</td>
<td>FLU-NasNOS</td>
<td>FluMist®</td>
<td>MedImmune</td>
</tr>
<tr>
<td>123</td>
<td>Influenza virus vaccine, H5N1, A/Vietnam/1203/2004 (national stockpile)</td>
<td>FLU-H5N1</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Red denotes new RPMS Short Name
RPMS Immunization Package

• New codes are included in Version 8.5 patch 5
  – Patch 5 will be released in the next week
• New codes will be inactive in the Vaccine Table
  – Sites must activate them to use them
• CVX code 111 – Flu-LAIV3 will be inactive
  – This is the trivalent LAIV (FluMist®) vaccine - will not be available this year
• Forecasting
  – Same as last year – begins August 1st, ends March 31st
  – 2 dose algorithm for children < 9 years included
Q: We are beginning flu vaccination now, and received some of the new vaccines (e.g. quadrivalent inactivated), but those codes aren’t yet available because patch 5 has not been released. What should we do?

A: For sites that are beginning influenza vaccination and are using products that are not currently in the RPMS Immunization Package (e.g. quadrivalent inactivated influenza vaccine, cell culture, and recombinant trivalent inactivated vaccines), we suggest you use one of the other inactive influenza codes – e.g. FLU-TIVhx– to document.

- Once Patch 5 is released and loaded:
  1. Change the lot# for the Flu-TIVhx by adding a z, and inactivate it.
  2. Add the lot # with the new, correct flu code
  3. In Lists and Letters, run a list of patients who received the lot # with the z (e.g. the lot# for FLU-TIVhx).
  4. Edit patient records to reflect correct code/lot#.

- Codes for the trivalent inactivated influenza vaccine (140, 141), intradermal (144) high dose (135) as well as the new quadrivalent live attenuated influenza vaccine (149 – Flu-nasal4) are currently in the Immunization Package Version 8.5*4, and can be used.
Lot Number: 12345

Lot Number: z12345
Vaccine: FLU-TIVhx
Sub-lot:
Status: Inactive
Expiration Date: JUN #), 2013
Manufacturer: Sanofi
Source:
Default NDC Code:

Starting Count: 100  Doses Unused: 49  Doses Used: 51
Low Supply Alert: 50  (calculated)

Facility:

Enter the date on which this Lot Number expires.

Press <PF1>H for help  Insert
But wait! There’s more!

• Go to Lists and Letters in the Patient Menu
• Change the following parameters:
  – Age group (e.g. 0 – 100 years)
  – Patient group – include Active AND Inactive
  – Lot # - enter the lot # WITH THE Z IN FRONT OF IT
    • Alternatively, if multiple lot #s, can enter the FLU-TIVHx code under “Immunizations Received” parameter
• This will give you a list of patients who received the flu vaccine coded as FLU-TIVhx
  – You can then choose “E” to edit each patient in that list – go into the patient record and edit the immunization visit to change the vaccine type and change the correct lot# (without the Z).
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Forecast/Clinic</td>
<td>06-Mar-2013</td>
</tr>
<tr>
<td>2</td>
<td>Age Range</td>
<td>0-100 Years</td>
</tr>
<tr>
<td>3</td>
<td>Patient Group</td>
<td>Active, Inactive</td>
</tr>
<tr>
<td>4</td>
<td>Community</td>
<td>ALL</td>
</tr>
<tr>
<td>5</td>
<td>Case Manager</td>
<td>ALL</td>
</tr>
<tr>
<td>6</td>
<td>Designated Provider</td>
<td>ALL</td>
</tr>
<tr>
<td>7</td>
<td>Immunizations Received</td>
<td>ALL</td>
</tr>
<tr>
<td>8</td>
<td>Immunizations Due</td>
<td>ALL</td>
</tr>
<tr>
<td>9</td>
<td>Health Care Facility</td>
<td>DEMO HOSPITAL</td>
</tr>
<tr>
<td>10</td>
<td>Lot Number</td>
<td>z12345</td>
</tr>
<tr>
<td>11</td>
<td>Additional Information</td>
<td>None</td>
</tr>
<tr>
<td>12</td>
<td>Order of Listing</td>
<td>by Patient Age</td>
</tr>
<tr>
<td>13</td>
<td>Include Deceased</td>
<td>No</td>
</tr>
</tbody>
</table>

Select a left column number to change an item.

List of Patients Print Due Letters Help

Select Action: Quit
Life is a delicate balance.

Your flu vaccine protects me.
My flu vaccine protects you.

Even healthy people can get the flu, and it can be serious. Everyone 6 months and older should get a flu vaccine.

Help protect Alaska from the flu.
Get vaccinated.

For more information, visit http://www.flu.gov
CDC Flu Materials for American Indians/Alaska Natives

Protect the Circle of Life
Your Flu Vaccine Protects Me
My Flu Vaccine Protects You

- The flu vaccine is safe. You can’t get the flu from a flu vaccine.
- The flu is the fourth leading cause of death among American Indian and Alaska Native elders.
- Please get a flu vaccine each year to protect you and your family.

Learn more at www.cdc.gov/flu or call 1-800-CDC-INFO

To order free copies: http://www.cdc.gov/flu/freeresources/print.htm
Resources

• Upcoming IHS Flu Webinars
  – IHS Clinical Rounds, Sept. 12th, 2 PM EDT
  – CHR Influenza Webinars – Sept. 13th, Oct. 2nd and Oct 7th, check website for times

• IHS Influenza Resources – www.ihs.gov/flu

• CDC Influenza resources – www.cdc.gov/flu

• CDC/ACIP Influenza Vaccination recommendations