Adult Immunization Update 2017 – Including Influenza
General Best Practice Guidelines for Immunization

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Melville
October 11, 2017

Disclosures

- Andrew Kroger is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation.

- I will discuss the off-label use of Tdap.

- I will not discuss a vaccine not currently licensed by the FDA.
Disclosures

- The recommendations to be discussed are primarily those of the Advisory Committee on Immunization Practices (ACIP):
  - Composed of 15 non-government experts in clinical medicine and public health.
  - Provides guidance on use of vaccines and other biologic products to DHHS, CDC, and the U.S. Public Health Service.

Next ACIP Meeting
October 25-26, 2017

http://www.cdc.gov/vaccines/acip/meetings/upcoming-dates.html

Overview

- 2017 Adult Immunization Schedules
- Influenza
- Meningococcal Recommendations
- General Best Practice Guidelines
- Resources
LAIV should not be used during the 2016–2017 influenza season

- Adults with egg allergy who have only hives should receive age-appropriate IIV or RIV.
- Adults with egg allergy other than hives, e.g., angioedema or respiratory distress, may receive age-appropriate IIV or RIV... in a medical setting.

Pregnant women should receive 1 dose of Tdap during each pregnancy, preferably during the early part of gestational weeks 27–36, regardless of prior history of receiving Tdap.

Special precautions:
- Adults diagnosed with HIV/AIDS who have not received antiretroviral therapy for at least 6 months before the influenza season, and who are being treated with HAART, may receive LAIV in a medical setting.
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Footnotes: Recommended immunization schedule for adults aged 10 years or older, United States 2017

1. Influenza vaccination

General information:
- All persons aged 6 months or older who do not have confirmed or suspected influenza vaccination with an age-appropriate influenza vaccine for the 2016–2017 influenza season, regardless of medical condition or risk for complications from influenza.
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Adult females through age 26 and adult males through age 21 (and males 22–26 who may receive vaccination) who initiated HPV vaccination series before age 15 and:

- **Received 2 doses at least 5 months apart** are considered adequately vaccinated and do not need additional dose of HPV vaccine

- **Received only 1 dose, or 2 doses less than 5 months apart,** are not considered adequately vaccinated and should receive 1 additional dose of HPV vaccine.

Adults in infancy and young childhood, who initiated HPV vaccination before age 15, received the following:

- **2 doses at least 5 months apart are considered adequately vaccinated** and do not need additional dose of HPV vaccine.

- **1 dose is not considered adequately vaccinated** and should receive 1 additional dose of HPV vaccine.

**Recommendations for HepB remain same, examples of chronic liver disease added**

- Anyone who wants protection from hepatitis B virus infection
- At risk – percutaneous/mucosal or sexual exposure, close contacts of HBsAg(+) cases, HIV, occupational, travel
- End-stage renal disease, dialysis
- Chronic liver disease – examples include hepatitis C virus infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
Adults with HIV infection... should receive 2-dose primary series of MenACWY at least 2 months apart... and revaccinate every 5 years

Young adults age 16–23 (preferred age 16–18) healthy and not at increased risk for serogroup B meningococcal disease may receive either 2-dose series of MenB-FHbp at 0 and 6 months or 2-dose series of MenB-4C at least 1 month apart

Adults at risk, e.g., asplenia, complement deficiency, microbiologists, outbreaks, should receive 3-dose series of MenB-FHbp at 0, 1–2, and 6 months... or 2-dose series of MenB-4C at least 1 month apart

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Seasonal Influenza update
INFLUENZA VACCINATION IN ADULTS

http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

Influenza Health Burden in the US

- Influenza disease burden varies year to year
  - Millions of cases
  - Average of 226,000 hospitalizations annually
    - >75% among adults
  - 3,000-49,000 deaths annually
    - >90% among adults

- Direct medical costs in U.S.: ~$10.4 billion
- Add in loss of work and life: ~$87 billion

Inactivated Influenza Vaccine Efficacy

- About 60% effective among healthy persons younger than 65 years of age
- 50-60% effective in preventing hospitalization among elderly persons
- 80% effective in preventing death among elderly persons
- 2015-16 estimate: 47% effective against medically attended, lab-confirmed influenza

Grohskopf LA, et al. MMWR Recomm Rep 2016;65(No. RR-5):[1-52].
http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6505.pdf

Influenza and Complications Among Nursing Home Residents*

* Inactivated influenza vaccine. Genesee County, MI, 1982-1983
Influenza Vaccines 2017-2018 Season

- Trivalent influenza vaccines will contain:
  - A/Michigan/45/2015 (H1N1)-like virus
  - A/Hong Kong/4801/2014 (H3N2)-like virus;
  - B/Brisbane/60/2008-like virus (B/Victoria lineage).

- Quadrivalent influenza vaccines will contain:
  - these antigens, and also
  - B/Phuket/3073/2013-like virus (Yamagata lineage)
Recent New Influenza Vaccine Licensures

- Afluria trivalent and quadrivalent (Seqirus) licensed for five years of age or older
- FluLaval licensed for 6 months – 35 months of age, but at “adult” volume
- An MF59-adjuvanted trivalent inactivated influenza vaccine (aIIV3), Flua (Seqirus, Holly Springs, North Carolina), was licensed by FDA in November 2015 for persons aged ≥65 years.
  - aIIV3 is an acceptable alternative to other vaccines licensed for persons in this age group.
- Quadrivalent formulation of Flucelvax (cell culture based inactivated influenza vaccine [ccIIV4], Seqirus), licensed by FDA in May 2016, for persons aged ≥4 years.
  - ccIIV4 is an acceptable alternative to other vaccines licensed for persons in this age group.

Vaccination of Adults 65 Years and Older

- High dose influenza vaccine
  - Inactivated trivalent vaccine – 4 times the antigen as standard dose (60 µg antigen per vaccine strain vs 15 µg in standard dose)
  - Licensed in December 2009 based on improved immunogenicity compared to standard dose for influenza A (H1N1) and A (H3N2) and non-inferior immune response for influenza B.
  - RCT found relative efficacy of high-dose relative to standard dose vaccine of 24% (CI 9.7-36.5) against laboratory confirmed influenza.
  - Cohort study by CMS comparing persons with a claim for standard versus high dose vaccine found 22% (CI 16-27%) reduction in influenza-related hospitalization.

References:
Vaccination of Adults 65 Years and Older

- **Adjuvanted inactivated trivalent influenza vaccine**
  - MF-59 adjuvant is oil-in-water emulsion
  - Licensed in Europe for many years
  - Licensed in US in November 2015 based on immunogenicity data for persons 65 years and older
  - No RCT in older adults, however clinical efficacy trial of quadrivalent MF-59 vaccine post-licensure required

- **Cohort study in Italy using administrative database estimated 25% (CI 2-43) lower risk influenza-related hospitalization for MF-59 adjuvanted vaccine vs non-adjuvanted**


Influenza vaccine coverage — Pregnant Women

Figure 1. Flu vaccination coverage before and during pregnancy among pregnant women by early November and mid-April for 2010-11 through 2016-17 flu seasons, Internet panel survey, United States

https://www.cdc.gov/flu/fluvaxview/pregnant‐women‐nov2016.htm

Interim Estimates of 2016–17 Seasonal Influenza Vaccine Effectiveness — United States, February 2017

- Report uses data, as of February 4, 2017

<table>
<thead>
<tr>
<th>Influenza type</th>
<th>Overall Adjusted Vaccine Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza A and B</td>
<td>48%</td>
</tr>
<tr>
<td>Influenza A</td>
<td>43%</td>
</tr>
<tr>
<td>Influenza B</td>
<td>73%</td>
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</tbody>
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MMWR 66(6); 167-171
https://www.cdc.gov/mmwr/volumes/66/wr/mm6606a3.htm?s_cid=mm6606a3_w
Shoulder Injury Related to Vaccine Administration

- Shoulder Injury Related to Vaccine Administration (SIRVA) was added to the Vaccine Injury Compensation Table in March 2017.
- It is an injury to the musculoskeletal structures of the shoulder, including the ligaments, bursae, and tendons.
  - SIRVA is thought to occur as a result of unintended injection of vaccine antigen and/or trauma from the needle going into and around the underlying bursa of the shoulder.
  - Symptoms include shoulder pain and limited range of motion after a vaccine injection.


Shoulder Injury Related to Vaccine Administration

- When administering a vaccine by IM injection in the deltoid muscle:
  - Use proper landmarks and technique to identify the injection site.
  - Use the proper needle length based on the age and size of the patient and injection technique.
  - Health care providers who administer vaccines should demonstrate their ability to properly locate the recommended injection sites and receive additional training as needed.
- Providers are encouraged to report any clinically significant adverse event after vaccination, including SIRVA, to VAERS  https://vaers.hhs.gov/index.html.

Egg Allergy Algorithm

- No longer printed in the MMWR

Meningococcal Vaccine Recommendation
Eculizumab Use

- Eculizumab – indicated for paroxysmal nocturnal hematuria and hemolytic uremic syndrome
- Simulates complement deficiency
- A high-risk indication for both MenACWY and MenB

Spacing of MenACWY with PCV13

- Applies to functional and anatomic asplenia AND HIV
- Applies to MenACWY-D
- If both vaccines are indicated, administer PCV13 series first and then MenACWY-D 4 weeks later
- If 4 week interval violated, administer repeat dose 4 weeks after the invalid dose
Mumps Disease and Outbreak Recommendations

- In 2016, 47 states and the District of Columbia in the U.S. reported mumps infections in 6,366 people.

- During mumps outbreaks, public health authorities may consider administering a third dose of MMR vaccine for specifically identified target populations, such as in schools, colleges, etc., who are in intense exposure settings that make it more likely for mumps to spread.
  - Criteria to consider prior to administering a third dose in a target population for mumps outbreak control include:
    - high two-dose vaccination coverage (i.e., vaccination coverage >90%);
    - intense exposure settings likely to facilitate transmission (e.g., schools, colleges, correctional facilities, congregate living facilities) or healthcare settings;
    - high attack rates (i.e., >5 cases per 1,000 population); and evidence of ongoing transmission for at least two weeks in the target population (i.e., population with the high attack rates).

Mumps Cases, U.S., 2016 and Role of MMR in Vaccine Outbreaks

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General Best Practice Guidelines
General Best Practice Guidelines

- Timing and spacing
- Contraindications and precautions
- Preventing and managing adverse reactions to immunization
- Vaccine administration
- Storage and handling
- Altered immunocompetence
- Special situations
- Vaccination records
- Vaccination programs
- Vaccine information sources
Timing and Spacing of Immunobiologics

- No interval between PCV13 and IIV

- 28 day interval between any MMR-containing vaccine and Varicella-containing vaccine (not zoster) – with no 4-day grace period allowed
  - General Guidelines – 4-day grace used between doses of the same vaccine
  - Cannot be applied to MMRV, because this vaccine contains single-use components that might interfere with each other (known that MMR affects the replication of VZV)

Contraindications and Precautions

- New definition of Precaution:
  - A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity

- Vaccination of Hospitalized Persons
  - Hospitalized persons can be vaccinated during their hospitalization if they are not moderately or severely acutely ill
    - Evidence weak to support an interval between vaccination and anesthesia or surgery
    - Many hospitals have performance indicators that incentivize providers to administer influenza vaccine during the hospitalization
    - CMS reporting requirement – Influenza vaccination of hospitalized patients
Preventing and Managing Adverse Reactions to Vaccination

- Descriptive information about anaphylactic allergy
  - Allergic reactions can include: local or generalized urticaria (hives) or angioedema; respiratory compromise due to wheezing or swelling of the throat; hypotension; and shock. Immediate-immunoglobulin E (IgE)–mediated (type 1) immune reactions, such as anaphylaxis, usually occur within minutes of parenteral administration and involve specific IgE interactions with discrete antigens.
  - Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is advised, even after complete resolution of symptoms and signs.

- Management for anaphylactic allergy
  - New Tables from Up To Date
  - Emphasis on epinephrine and protocols for contacting Emergency Medical Services

Coming from ACIP October 25-26, 2017

- Vote on use of adjuvanted inactivated shingles vaccine
- Vote on two-dose adult Hepatitis B vaccine
- Vote on Child and Adult Schedules
- Discussion about CDCs campaign for safe adult IM vaccine administration
Resources

CDC Resources for Staff Education

- Competency-based education for staff is critical
- Multiple education products available free through the CDC website:
  - Immunization courses (webcasts and online self-study)
  - Netconferences
  - You Call the Shots self-study modules
- Continuing education credits available

https://www.cdc.gov/vaccines/ed/index.html
Safe and Effective Vaccine Administration: An Education Campaign for Health Care Personnel

Andrew Kroger, MD, MPH
Communication and Education Branch, ISD, NCIRD, CDC

- CDC is launching a campaign about proper intramuscular (IM) vaccine administration to avoid shoulder bursitis
- Campaign will coincide with beginning of influenza vaccination season, on or about August 31, 2017
- 2017-18 influenza vaccination season: Up to 166 million doses of influenza vaccine expected for distribution in 2017-18
- Preliminary data from both the Vaccine Adverse Events Reporting System and the National Vaccine Injury Compensation Program indicate reporting has increased in the last several years
Shoulder Bursitis

- Thought to result from the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder

- The Institute of Medicine (IOM) reviewed the scientific and medical literature finding that the evidence convincingly supported a causal relationship between vaccine administration and “deltoid bursitis”

- Descriptive information added to the Vaccine Injury Table in March, 2017
Campaign materials include:

- Comprehensive vaccine administration information
- a short video on the correct technique for intramuscular injection
- new vaccine administration e-Learn.
- An infographic on administering flu vaccine to an adult

Now Available

- Supplemental information regarding:
  - Human Papillomavirus
  - Meningococcal Disease
  - Pneumococcal Disease

https://www.cdc.gov/vaccines/pubs/pinkbook/supplement.html
https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
CDC Vaccine and Immunization Resources

Questions? Email CDC

- Providers
  nipinfo@cdc.gov
- Parents and patients
  www.cdc.gov/cdcinfo

Website
  www.cdc.gov/vaccines

Twitter
  @DrNancyM_CDC

Influenza
  www.cdc.gov/flu

Vaccine Safety
  www.cdc.gov/vaccinesafety

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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You Call the Shots
(Several Modules Added or Updated)

https://www.cdc.gov/vaccines/ed/youcalltheshots.html