Immunization Update 2013

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Centers for Disease Control and Prevention

American Academy of Pediatrics
Connecticut Chapter
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Disclosures

- No financial conflict or interest with the manufacturer of any product named during this presentation.
- I will present recommendations for tetanus-toxoid, diphtheria-toxoid, acellular pertussis (Tdap) vaccine, human papillomavirus vaccine (HPV), and influenza vaccines in an off-label manner.
Overview

- 2013 Immunization schedules
- New MMR recommendations
- HPV vaccine
- Tdap (pregnancy)
- Influenza vaccines
- Storage and handling
- Vaccine administration

* Citations,
Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – 2013. (FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>19-23</th>
<th>2-3 yrs</th>
<th>4-6 yrs</th>
<th>7-10 yrs</th>
<th>11-12 yrs</th>
<th>12-15 yrs</th>
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<tr>
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<td>Annual vaccination (9Y only)</td>
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<td>Annual vaccination (IV or IAV)</td>
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<td>Mumps, Measles, Rubella (MMR)</td>
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This schedule includes recommendations in effect as of January 1, 2013. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO (800-232-4636)).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.
Measles-Mumps-Rubella Vaccine
New MMR Recommendations –

- **Children with HIV**
  - Recommended age for 2nd dose – 4 – 6 years
  - Definition of severe immunosuppression
  - Recommendations for Children with perinatal HIV who received MMR vaccine before combination Anti-retroviral Therapy (cART)

- **General criteria of immune/susceptible – adults**

- **Recommendation for use of passive immunobiologics**
Severe Immunosuppression

- ABSENCE OF SEVERE IMMUNOSUPPRESSION
- Children 5 years old or younger
  - CD4 T-lymphocyte percentage ≥ 15 for 6 months or longer
    preferred metric
  - CD4 T-lymphocyte counts above sliding scale parameters for 6 months or longer (value varies by age (see text for details))
- Persons older than 5 years
  - CD4 T-lymphocyte count greater than 200 cells/mm$^3$ for 6 months or longer
    Preferred metric
  - CD4 T-lymphocyte percentage ≥ 15 for 6 months or longer

www.cdc.gov/mmwr/pdf/rr/rr6204.pdf
Revaccination with MMR

- A revaccination dose of MMR vaccine should be given to children infected with HIV in the perinatal period who received MMR vaccine before establishment of combined Anti-retroviral Therapy (cART)
- Use the same parameters for absence of severe immunosuppression
  - Add 6 months of cART therapy prior to revaccination
Criteria of Immunity

- Physician diagnosis of measles, mumps, or rubella can NO LONGER be used as a criteria of immunity
- Applicable generally to adults with no history of MMR vaccine series in childhood
- Lowers the threshold for administering a dose to adults
Post-exposure Prophylaxis for Measles

- Previously two concentrations of IGIM were recommended, depending on whether the contact was immunocompromised.
- Now use higher concentration (immunocompromised level) for healthy contacts
  - Dose = 0.5 mL/kg IGIM
- MMR recommended for infants 6 – 12 months for post-exposure prophylaxis for measles
- IGIM recommended for infants younger than 6 months for post-exposure prophylaxis for measles
Post-exposure Prophylaxis for Measles

- For immunocompromised contacts, use IGIV for post-exposure prophylaxis for measles
- 400 mg/kg
- If IGIV is being administered routinely, a recent dose (within past 3 weeks) is sufficient to prophylax for measles exposure (i.e. another dose of IGIV not needed)
- If IGSC is administered in past 2 weeks, same rule applies
HUMAN PAPILLOMAVIRUS VACCINES (HPV)

FDA License of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP)

On October 16, 2006, the Food and Drug Administration licensed the second human papillomavirus (HPV) vaccine, Gardasil (Merck & Co., Inc.) for use in males aged 11 through 18 years for prevention of genital warts caused by human papillomavirus (HPV) types 6 and 11. HPV-16 and -18-related cancers and genital warts are significantly reduced in young men who received Gardasil compared with those who did not. In addition, the Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of males aged 11 to 12 years and catch-up vaccination for 13-year-olds (ACIP, 2008). Men who have sex with men or have multiple sexual partners should be vaccinated. HPV vaccine is recommended for all men aged 21 to 26 years who have not been previously vaccinated (ACIP, 2008). The Advisory Committee on Immunization Practices recommends vaccination of all men aged 21 to 26 years in those with coexisting conditions such as HIV infection, sexually transmitted infections, and precancerous anogenital lesions. The ACIP also recommends vaccination of men aged 21 to 26 years who have not been vaccinated but have sex with men or have multiple sexual partners. The Advisory Committee on Immunization Practices recommends Gardasil for routine vaccination of all men aged 11 to 12 years and catch-up vaccination for 13-year-olds. Men who have sex with men or have multiple sexual partners should be vaccinated. HPV vaccine is recommended for all men aged 21 to 26 years who have not been previously vaccinated. The Advisory Committee on Immunization Practices recommends vaccination of all men aged 21 to 26 years in those with coexisting conditions such as HIV infection, sexually transmitted infections, and precancerous anogenital lesions. The ACIP also recommends vaccination of men aged 21 to 26 years who have not been vaccinated but have sex with men or have multiple sexual partners.

http://www.cdc.gov/vaccines/pubs/ACIP-list.htm#hpv
# Comparing HPV Vaccines

<table>
<thead>
<tr>
<th></th>
<th>HPV4 (Gardasil)</th>
<th>HPV2 (Cervarix)</th>
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<tr>
<td><strong>Types</strong></td>
<td>6, 11, 16, 18</td>
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<tr>
<td><strong>Recommendations for</strong></td>
<td><strong>Females</strong></td>
<td><strong>Males</strong></td>
</tr>
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<td></td>
<td>Routine: 11-12 yrs</td>
<td>Routine: 11-12 yrs</td>
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<td></td>
<td>Catch-up: 13-26 yrs</td>
<td>Catch-up: 13-26* yrs</td>
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<td><strong>Recommendations for</strong></td>
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<td>Do not administer to males</td>
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<td>Routine: 11-12 yrs</td>
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<td>Catch-up: 13-21 yrs</td>
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<td>Immunocompromised: 11-26 yrs</td>
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<td>MSM: 11-26 yrs</td>
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<tr>
<td><strong>Route</strong></td>
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</table>

*ACIP off-label recommendation
HPV Series Completion

- Significant number of girls who began the HPV series do not receive all three doses

- Related factors include parents’ understanding
  - vaccine not needed (19.1%);
  - vaccine not recommended (14.2%);
  - vaccine safety concerns (13.1%);
  - lack of knowledge about the vaccine or the disease (12.6%);
  - daughter is not sexually active (10.1%)

MMWR 2013; 62 (No. 29) July 26, 2013
**HPV Immunization Rates**

**13-17 Years of Age**

<table>
<thead>
<tr>
<th>HPV Vaccine</th>
<th>2011</th>
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</thead>
<tbody>
<tr>
<td>1 or more doses*</td>
<td>53.0%</td>
<td>53.8%</td>
</tr>
<tr>
<td>3 dose series completion **</td>
<td>34.8%</td>
<td>33.4%</td>
</tr>
</tbody>
</table>

*Percentages ≥1 human papillomavirus vaccine, either HPV4 or HPV2 reported among females only (n=11,2360)

** ≥3 doses of human papillomavirus vaccine, either quadrivalent or bivalent.

84.0% of HPV-unvaccinated girls have had a missed opportunity in 2012.

If these girls had received the HPV vaccine during visits when another vaccine was given, coverage with at least 1 dose of HPV...
Strategies for Increasing HPV Vaccination Rates in Clinical Practices

- Recommend HPV vaccine
  - include HPV vaccine when discussing other needed vaccines

- Integrate standard procedures
  - assess for needed vaccines at every clinical encounter
  - immunize at every opportunity
  - standing orders

- Use reminder and recall

Tools for improving uptake of HPV: www.cdc.gov/vaccines/teens
Strategies for Increasing HPV Vaccination Rates in Clinical Practices

- Use AFIX (assessment, feedback, incentives, eXchange of information)
- Report to registry
- HEDIS measure (Jan 2012)
  - proportion of 13-year-old girls who have not received 3 doses

Tools for improving uptake of HPV: www.cdc.gov/vaccines/teens
HPV Vaccination

Human Papillomavirus (HPV)

At a glance:

Human Papillomavirus (HPV) is a common virus that is spread through sexual contact. Most of the time HPV has no symptoms so people do not know they have it.

There are approximately 40 types of genital HPV. Some types can cause cervical cancer in women and can also cause other kinds of cancer in both men and women. Other types can cause genital warts in both males and females. The HPV vaccine works by preventing the most common types of HPV that cause cervical cancer and genital warts. It is given as a 3-dose vaccine.

What You Should Know:

- About the Disease
- Vaccine Information
- Vaccine Safety
- Who Should Not be Vaccinated?

For Health Professionals:

- Clinical
- Recommendations
- References & Resources
- Provider Education
- Materials for Patients

Additional Resources:

http://www.cdc.gov/vaccines/vpd-vac/hpv/default.htm
Pertussis
**Tdap Vaccines**

- 2 vaccines available licensed for different age groups

- **Boostrix (GlaxoSmithKline)**
  - **NEW!** Approved for persons 10 years of age and older
  - Single dose

- **Adacel (sanofi pasteur)**
  - Approved for persons 11-64 years of age
  - Single dose
General Principles for Use of Tdap

- Tdap preferred to Td to provide protection against pertussis
- Both vaccines approved as a single dose
Tdap-naïve Women and Pregnancy

• Providers of pregnant women should recommend Tdap to their patients

• This strategy is preferred to cocooning, but if Tdap cannot be given in pregnancy it can be given in postpartum period
Pregnancy and Repeat Tdap Doses

• Pregnant women should receive Tdap with each pregnancy

• Ideal time is 27-36 week gestational age
Influenza

Interim Recommendations: Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2013

Influenza Prevention and Control Recommendations

Introduction
This document summarizes recommendations for the use of influenza vaccines approved on February 21, 2013 by the Advisory Committee on Immunization Practices (ACIP). An expanded 2013 ACIP influenza vaccination recommendation statement will be published in MMWR Recommendations and Reports prior to the start of the 2013-2014 influenza season. Providers should consult the expanded 2013 ACIP influenza vaccination statement when available for complete and updated information.

Note on Influenza Vaccine Abbreviations
This document includes revised abbreviations to refer to currently available influenza vaccines (also available at ACIP Abbreviations for Vaccines):

- The abbreviation TIV (Trivalent Influenza Vaccine, previously used for inactivated influenza vaccines) has been replaced with the abbreviation IIV (Inactivated Influenza Vaccine). For 2013-2014, IIVs as a class will include:
  - egg-based and cell culture-based trivalent inactivated influenza vaccine (IIV3); and
  - egg-based quadrivalent inactivated influenza vaccine (IIV4).
- RIV refers to recombinant hemagglutinin influenza vaccine, which will be available as a trivalent formulation (RIV3) for 2013-2014.
- LAIV refers to live, attenuated influenza vaccine, which will be available as a quadrivalent formulation (LAIV4) for 2013-2014.
- LAIV, IIV, and RIV denote vaccine categories; numeric suffix specifies the number of influenza virus antigens contained in...
Influenza Vaccines for 2013-14

- **Inactivated (IIV, formerly TIV)**
  - intramuscular or intradermal
  - trivalent (IIV3, cclIV3, RIV3) or quadrivalent (IIV4)
    - A/H1N1, A/H3N2, one or two B strains
  - duration of immunity one year or less

- **Live attenuated influenza vaccine (LAIV)**
  - nasal spray
  - quadrivalent only (LAIV4)
  - duration of immunity at least one year
<table>
<thead>
<tr>
<th>Product</th>
<th>Indications</th>
<th>Type/ antigens</th>
<th>Presentation</th>
<th>Route</th>
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<tbody>
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<td>Fluarix</td>
<td>3 yrs and older</td>
<td>IIV4</td>
<td>MF Syringe</td>
<td>IM</td>
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<tr>
<td>FluLaval</td>
<td>3 yrs and older</td>
<td>IIV4</td>
<td>MD Vial</td>
<td>IM</td>
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<td>FluBlok</td>
<td>18 thru 49 yrs</td>
<td>RIV3</td>
<td>SD Vial</td>
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<td>Flucelvax</td>
<td>18 yrs and older</td>
<td>IIV3</td>
<td>MF Syringe</td>
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<td>FluMist</td>
<td>2 thru 49 yrs healthy; not pregnant</td>
<td>LAIV4</td>
<td>MF Sprayer</td>
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<tr>
<td>Fluzone</td>
<td>6 months and older</td>
<td>IIV4</td>
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# Influenza Vaccine Presentations 2013-2014

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<th>Name</th>
<th>Manufacturer</th>
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<th># Antigens</th>
<th>Presentation</th>
<th>Route</th>
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<td>CSL</td>
<td>5 and older</td>
<td>Trivalent</td>
<td>Pre-Filled Syringe</td>
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Available at [http://www.cdc.gov/flu/protect/vaccine/vaccines.htm](http://www.cdc.gov/flu/protect/vaccine/vaccines.htm)
Choice of Influenza Vaccine

- The choice should primarily be driven by the age-indication and contraindications and precautions

- Where more than one type of vaccine is appropriate and available, ACIP has no preferential recommendation for use of any influenza vaccine product over another
  - Quadrivalent vs trivalent
  - High-dose vs standard dose
  - IIV vs LAIV in any age group for whom either is indicated
Influenza Vaccination Schedule

- Annual vaccination for persons 6 months of age and older without contraindications or precautions

- IIV dosage varies by age
  - 6 months through 35 months 0.25 ml
  - 3 years and older 0.5 mL

- Administer 1 dose per season to persons 9 years of age and older

- Some children 6 months through 8 years of age will need 2 doses
One Dose or Two?
Vaccine for Children 6 Months Through 8 Years

- Children aged 6 months through 8 years require 2 doses in the first season they are vaccinated.
- If previously vaccinated, need to have received 2009(H1N1)-containing vaccine (2009 monovalent, or 2010-11, 2011-12, or 2012-13 seasonal vaccines).
- This season (as the last), there are two acceptable approaches for determining the number of doses.
- These differ in whether or not vaccination history prior to the 2010-2011 season is considered.

Dose Algorithm for 6 Months Through 8 Year Olds

* Doses should be administered a minimum of 4 weeks apart.

- If vaccination history before 2010–11 is available
- If child received
  - 2 or more seasonal influenza vaccines during any previous season,
  - And at least 1 dose of a 2009(H1N1)-containing vaccine (monovalent 2009(H1N1) or 2010-11, 2011-12 or 2012-13 seasonal vaccine),
  - Then the child needs only 1 dose in 2013–14

Need only 1 dose of vaccine in 2013–14 if:
  - ≥2 doses of seasonal influenza vaccine since July 1, 2010; or
  - ≥2 of seasonal influenza vaccine before July 1, 2010, and ≥1 dose of monovalent 2009(H1N1) vaccine; or
  - ≥1 dose of seasonal influenza vaccine before July 1, 2010, and ≥1 dose of seasonal influenza vaccine since July 1, 2010.

Influenza Vaccination for Persons with Egg Allergies—2013-14

Can the individual 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 individual experience ONLY hives?

- Yes: 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

- No: Administer RIV3, if patient aged 18 through 49 yrs.; OR Refer to a physician with expertise in management of allergic conditions for further evaluation

ACIP recommendation, publication pending
Influenza Vaccination for Persons with Egg Allergies—2013-14: Second Modification

Addition of the following:

- For individuals with 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 18 through 49 years of age

ACIP recommendation, publication pending
CDC recommends vaccines be stored in stand-alone refrigerator and freezer units rather than combination units

- The refrigerator compartment of a combination unit may be used to store refrigerated vaccines and a separate freezer unit to store frozen vaccines

- **Storage units should have**
  - Enough room to store the year’s largest inventory without crowding;
  - Sufficient room to store water bottles (refrigerator) or frozen coolant packs (freezer);
  - Frost free or automatic defrost units are preferred

www.cdc.gov/vaccines/recs/storage/toolkit/default.htm
Storage Unit Guidance

- CDC does not recommend use of a “dormitory-style” unit for ANY vaccine storage including temporary storage
  - Dorm-style = freezer compartment with no exterior door or thermostat controls
  - Increased risk of exposing vaccines to freezing temperatures
  - NIST studies have shown there is no “good” vaccine storage area in a dorm-style unit
Updated Thermometer Recommendations

- CDC recommends using a calibrated, digital thermometer with a biosafe glycol-encased probe or a similar temperature buffered probe
  - These more accurately reflect the temperature of the vaccine vial
  - Place the probe with the vaccine in the part of the unit where recommended storage temperatures are best maintained
  - Probes should be detachable from the digital display
Storage and Handling Practices

- Storage unit temperatures should be read and documented twice each workday.
- The min/max temperature should be read and documented once per workday preferably in the morning.
- Stored temperature monitoring data should be downloaded and reviewed weekly.
- Weekly review of vaccine expiration dates and rotation of vaccine stock.
**Vaccine Administration Errors**

**Vaccine Error**

Any preventable event that may cause or lead to inappropriate use of a vaccine or cause patient harm

- No one wants to make an error
Rights of Medication Administration

- Right patient
- Right vaccine and diluent
- Right time (age, interval, expiration time/date)
- Right dosage
- Right route (correct needle gauge and length and technique)
- Right site
- Right documentation
Vaccine Route

- Oral
- Intranasal
- Subcutaneous
- Intradermal
- Intramuscular
Staff Training and Education

- All personnel who administer vaccines (permanent and temporary) should receive comprehensive, competency based training before administering vaccines. Providers need to validate staff’s knowledge and skills with a skills checklist.

- Integrate training into:
  - new staff orientation
  - annual education requirements
  - when vaccine administration recommendations are updated or when new vaccines are added
Thank You

Email: nipinfo@cdc.gov

CDC-INFO Website www.cdc.gov/info

Website: www.cdc.gov/vaccines