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Key Inforbits

- New Childhood Immunization Schedules
- New Tdap Recommendations for Adults
- Update to Rabies Post Exposure Prophylaxis
- Quadrivalent HPV Vaccine in Males
- Vero-cell-culture-derived trivalent flu vaccine trial
- Travel Vaccine Tidbits

Updates in Immunization Literature and Recommendations

Updated Immunization Schedules for Infants, Children, and Adolescents

On February 1, the Centers for Disease Control and Prevention (CDC) released annual updates to the vaccination schedules.

Vaccine	Changes
Pneumococcal	• Prevnar 13 replaces Prevnar 7-valent pneumococcal conjugate vaccine • Prevnar 13 may also be used to complete a vaccination series started with Prevnar 7
Meningococcal (MCV_4)	• Booster dose should be given to adolescents at 16 years • Children age 2-10 years of age with persistent complement component deficiency or functional or anatomic asplenia should receive a routine two-dose primary series with a booster dose every 5 years • People infected with HIV should receive two doses of MCV_4 at least 8 weeks apart
Tetanus, diphtheria toxoids, and acellular pertussis (Tdap)	• A single dose of Tdap is recommended in children 7-10 years of age that are incompletely immunized against pertussis or whose pertussis vaccination status is unknown
Trivalent influenza	• Children 6 months to 8 years, should receive two doses of the trivalent influenza vaccine, if they have not previously received 2 doses of the monovalent H1N1 influenza vaccine.
Hepatitis B (HepB)	• Infants who did not receive a birth dose should receive 3 doses on a schedule of 0, 1, and 6 months

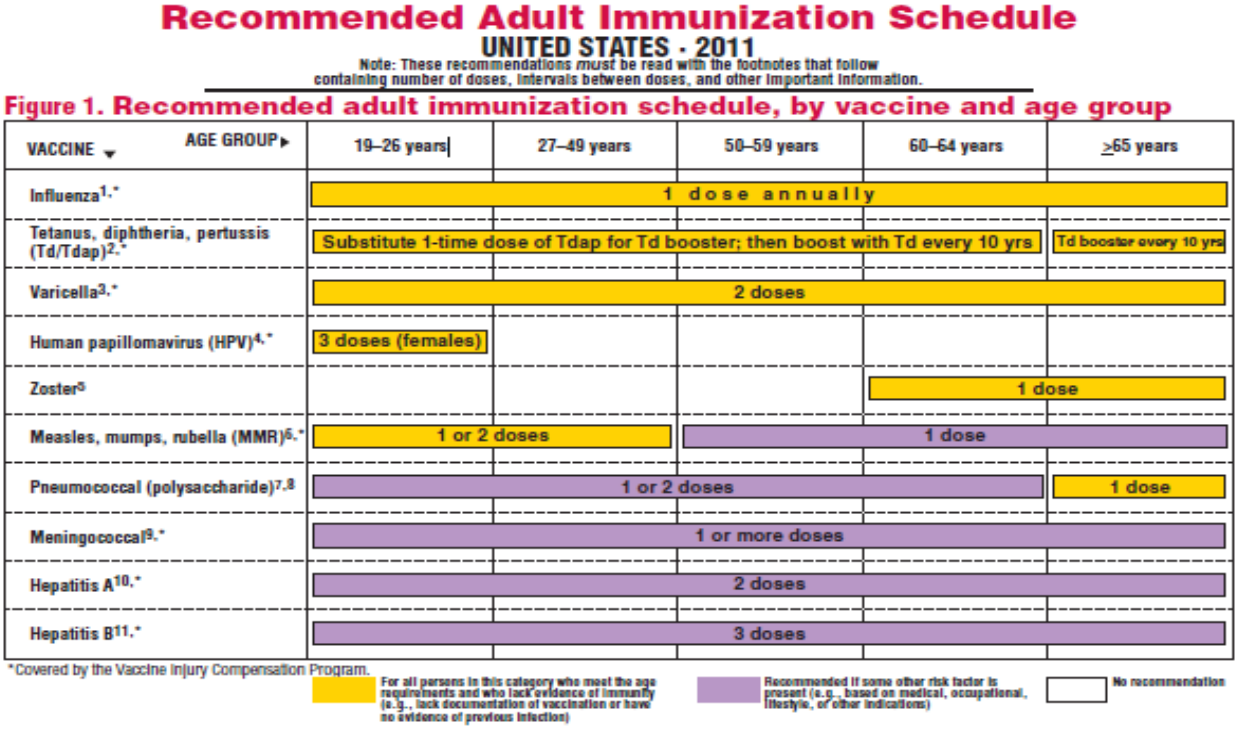
1. Immunization Schedules updated for infants, children, adolescents. ASHP News Release. 2011 Feb 2. http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=3479
2. Immunization Schedules [Internet]. Atlanta: Centers for Disease Control and Prevention;c2011. Recommended Immunization Schedule for Persons Aged 0 Through 6 Years; 2011 Feb 1 [cited 2011 Feb 23] Available from: http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#hcp

3. Immunization Schedules [Internet]. Atlanta: Centers for Disease Control and Prevention;c2011. Recommended Immunization Schedule for Persons Aged 7 Through 18 Years; 2011 Feb 1 [cited 2011 Feb 23] Available from: http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#hcp

New Immunization Recommendations to Improve Control of Pertussis

In 2009, over 16,000 cases of pertussis were reported to the CDC, and 12 infant deaths were attributed to the infection. A 2010 outbreak of pertussis in California caused over 8,000 cases and led to 10 infant deaths. Despite 2005 recommendations for the use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) in adolescents and adults, Tdap coverage is 56% in adolescents and < 6% in adults. The Advisory Committee on Immunization Practices (ACIP) approved new recommendations of Tdap to include the use of Tdap (1) regardless of interval since the last tetanus or diphtheria-toxoid vaccine, (2) in certain adults aged 65 years and older, and (3) in undervaccinated children aged 7 through 10 years. Adults aged 65 and older who should receive Tdap include those who anticipate contact with an infant less than 12 months old, and those who have previously not received a dose of Tdap. As in previous guidelines, Tdap is still indicated to replace one dose of Td, and patients should continue to receive a Td booster every 10 years. The revised immunization schedule for adults is included below.

1. Vaccines and Immunizations [Internet]. Atlanta: Centers for Disease Control and Prevention;c2011. Immunization Works January 2011 Issue; 2011 Jan [cited 2011 Feb 23] Available from: http://cdc.gov/vaccines/news/newsltrs/imwrks/2011/201101.htm



1. Immunization Schedules [Internet]. Atlanta: Centers for Disease Control and Prevention;c2011. Recommended Immunization Schedule for Adults; 2011 Feb 1 [cited 2011 Feb 23] Available from: http://cdc.gov/vaccines/recs/schedules/default.htm#adult

Update to Rabies Post Exposure Prophylaxis Vaccine Recommendations

In the past, persons unvaccinated with the rabies vaccine were recommended to have 5 1-mL doses immediately after exposure and on days 3, 7, 14, and 28. The CDC's Advisory Committee on Immunization Practices (ACIP) identified no adverse events correlated to failure to complete the 5th vaccine, and omission of that dose could reduce adverse events associated with each vaccine administration.

The new recommendation for unvaccinated patients is 4 1-mL doses of human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV) administered intramuscularly in the deltoid for adults or anterolateral thigh for small children and infants. Administration of the first dose should occur as soon as possible after exposure in conjunction with the rabies immunoglobulin (RIG). The remaining vaccines should be administered on days 3, 7, and 14 after the first vaccination. For patients that have been previously immunized post exposure prophylaxis consists of two 1-mL doses of HDCV or PCECV on days 0 and 3 without a dose of RIG.

1 Rabies Vaccines [Internet]. Atlanta: Centers for Disease Control and Prevention; c2010. Recommended Post Exposure Prophylaxis; 2010 March 22 [cited 2011 Feb 28] Available from: http://www.cdc.gov/rabies/medical_care/vaccine.html\

2 Rabies [Internet]. Atlanta: Centers for Disease Control and Prevention; c2010. Rabies Homepage;2010 Nov 2[cited 2011 Feb 28] Available from: http://www.cdc.gov/rabies/medical_care/index.html

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Efficacy of Quadrivalent HPV Vaccine against HPV Infection and Disease in Males

The *New England Journal of Medicine* recently published a study evaluating the safety and efficacy of the quadrivalent human papillomavirus (HPV) vaccine in boys and men. The study was a randomized, placebo-controlled, double-blind trial that enrolled 4065 healthy boys and men ages 16 to 26 years from 18 different countries who prior to enrollment tested negative for HPV. The primary efficacy objective was to demonstrate that the HPV vaccine reduced the incidence of external genital lesions related to HPV-6, 11, 16, or 18. Subjects were randomly assigned to receive either the vaccine or placebo on day 1, month 2, and month 6, and the median follow-up period after administration of the first dose of either vaccine or placebo was 2.9 years. The primary end point was the presence or absence of external genital lesions associated with HPV-6, 11, 16, or 18.

In the intention-to-treat population, 36 external genital lesions were seen in the vaccine group, and 89 in the placebo group resulting in an observed efficacy of 60.2% (95% CI 40.8-73.8). There was a significant reduction in the number of external lesions associated with HPV-6 (59.4%; 95% CI 31.2 to 76.8) and HPV-11 (76.3%, 95% CI, 40.8 to 92.0), but reductions were non-significant for HPV-16 (70.3%; 95% CI -5.5 to 94.7) and HPV-18 (33.9%; 95% CI, -476.7 to 94.5). Injection-site pain was significantly more frequent among patients receiving the vaccine versus those receiving placebo (57% vs. 51%, $p<0.001$).

Thus, the authors concluded that the quadrivalent HPV vaccine prevents infection with HPV-6, 11, 16, and 18, and the development of related external genital lesions in males between age 16 and 26.

1. Giuliano A, Palefsky , Goldstone S, et al. Efficacy of quadrivalent HPV vaccine against HPV infection and Disease in Males. *N Engl J Med*. 2011;364:401-11.

Efficacy, safety, and immunogenicity of a Vero-cell-culture-derived trivalent influenza vaccine: a multicentre, double-blind, randomized, placebo control trial

Recently *The Lancet* published an online article about the safety, efficacy and immunogenicity of a trivalent, split Vero-cell-derived seasonal influenza vaccine. Cell-derived vaccines can be used by patients with egg allergies and have faster replication time compared to standard vaccine production, allowing for flexibility when preparing for pandemic flu. The Phase 3 trial was a double-blind, placebo-control trial that randomized 7250 healthy adults (aged 18-49 years) at 36 U.S. centers, to receive either an injection of the placebo (n=3624) or the Vero-cell-culture-derived influenza vaccine(n=3626) during the 2008-2009 season. The objective was to determine the efficacy of the Vero-cell derived influenza vaccine in the prevention of culture confirmed influenza infection antigenically matched to one of the strains.

Participants had blood drawn for assessments of pre-vaccination H1 titers. Then they were given a diary to record their temperatures or other adverse experiences within the first 21 days after vaccination. Participants returned to the study site at 18-24 days after vaccination for a second blood draw for measurement of post-vaccination H1 titers and review of their diaries. The primary outcome showed the

influenza vaccine group had 13 antigenically matched influenza infections (0.4 %) compared to 60 infections (1.7%) in the placebo group. Overall protective efficacy for antigenically matched influenza infection was 78.5 % (95% CI 60.8-88.2).

Immunogenicity to the vaccine showed geometric mean titers increased in the vaccine group from before to 21 days after immunization. The most common adverse event reported with the influenza vaccine was injection site pain (43%) vs. placebo (8%) (95% CI 5.1-6.5). The authors concluded the trivalent, split Vero-cell-derived vaccine was safe, well tolerated, and provided protection in healthy adults against seasonal infection with the influenza vaccine.

1. Barrett PN, Berezuk G et al. Efficacy, safety, and immunogenicity of a Vero-cell-culture-derived trivalent influenza vaccine: a multicentre, double-blind, randomized, placebo control trial. Lancet [Internet]. 2011 Feb 26. [Cited 2011 Feb 22]; 377(9767):751-759. Available from http://thelancet.com/

Travel Vaccine Tidbits

- **You should see your medical provider 4 to 6 weeks before you travel**, but if < 4 weeks before travel, you should still see your doctor.
- The three categories of travel vaccines including (1) routine (vaccines in the regular immunization schedule, which protect against disease that are still common in other parts of the world), (2) recommended (vaccines for specific destinations intended to protect travelers and to prevent international spread of disease), and (3) required (vaccines required by International Health Regulations for specific destinations, and those required by the governments of certain countries)
- There are specific recommendations for travelers who are immunocompromised, pregnant or breastfeeding, and infants or children.
- The recommendations for specific destinations throughout the world can be found at http://wwwnc.cdc.gov/travel/destinations/list.aspx

1. Overview: Travelers' Health [Internet]. Atlanta Centers for Disease Control and Prevention ;c2011 [cited 2011 Feb 23] Available from: http://wwwnc.cdc.gov/travel/content/vaccinations.aspx

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Resources for more information about immunization:

- CDC Vaccines and Immunizations Homepage: http://www.cdc.gov/vaccines/default.htm
- Adult Immunization Schedules: http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm
- Childhood and Adolescent Immunization Schedules: http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable

The last "dose" …

"The democracy will cease to exist when you take away from those who are willing to work and give to those who would not."
Thomas Jefferson [1743 – 1826]

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