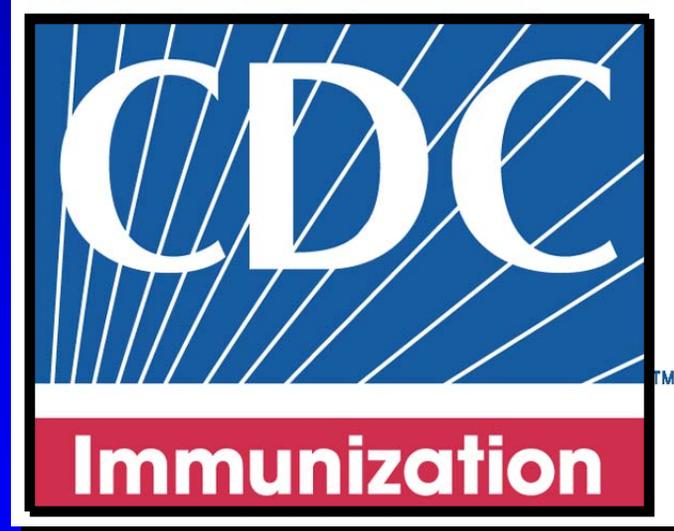


# **New Vaccines and New Recommendations**

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National Center for Immunization and  
Respiratory Diseases**



**April 1, 2010**

# Disclosures

- **William Atkinson is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation**
- **The speaker will discuss the off-label use of meningococcal conjugate and pneumococcal conjugate vaccines in a manner not approved by the FDA but recommended by ACIP**
- **The speaker will not discuss a vaccine not currently licensed by the FDA**

# New and Revised ACIP Recommendations

- 2010 immunization schedules
- Meningococcal conjugate revaccination
- HPV2 and HPV4 for males
- PCV13
- Influenza
- Age and interval for the last dose of IPV
- Japanese Encephalitis vaccines
- 4-dose rabies vaccine schedule

## Recommended Immunization Schedules for Persons Aged 0 Through 18 Years – United States, 2010

The Advisory Committee on Immunization Practices (ACIP) annually publishes an immunization schedule for persons aged 0 through 18 years that summarizes recommendations for currently licensed vaccines for children aged 18 years and younger and includes recommendations in effect as of December 15, 2009. Changes to the previous schedule (1) include the following:

- The statement concerning use of combination vaccines in the introductory paragraph has been changed to reflect the revised ACIP recommendation on this issue (2).
- The last dose in the inactivated poliovirus vaccine series is now recommended to be administered on or after the fourth birthday and at least 6 months after the previous dose. In addition, if 4 doses are administered before age 4 years, an additional (fifth) dose should be administered at age 4 through 6 years (3).
- The hepatitis A footnote has been revised to allow vaccination of children older than 23 months for whom immunity against hepatitis A is desired.

The National Childhood Vaccine Injury Act requires that health-care providers provide parents or patients with copies of Vaccine Information Statements before administering each dose of the vaccines listed in the schedules. Additional information is available from state health departments and from CDC at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>.

Detailed recommendations for using vaccines are available from ACIP statements (available at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>) and the 2009 *Red Book* (6). Guidance regarding the Vaccine Adverse Event Reporting System form is available at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

### References

1. CDC. Recommended immunization schedules for persons aged 0–18 years—United States 2009. *MMWR* 2009;57(51&52).
2. CDC. ACIP Provisional recommendations for the use of combination vaccines. Atlanta, GA: US Department of Health and Human Services, CDC; 2009. Available at <http://www.cdc.gov/vaccines/recom/provisional/downloads/combo-vax-aug2009-508.pdf>. Accessed November 18, 2009.
3. CDC. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP) regarding routine poliovirus vaccination. *MMWR* 2009;58:929–30.

# Recommended Adult Immunization Schedule – United States, 2010

**MMWR**<sup>TM</sup>

**QuickGuide**

Weekly

January 15, 2010 / Vol. 59 / No. 1

The Advisory Committee on Immunization Practices (ACIP) annually reviews the recommended Adult Immunization Schedule to ensure that the schedule reflects current recommendations for the licensed vaccines. In October 2009, ACIP approved the Adult Immunization Schedule for 2010, which includes several changes. A bivalent human papillomavirus vaccine (HPV2) was licensed for use in females in October 2009. ACIP recommends vaccination of females with either HPV2 or the quadrivalent human papillomavirus vaccine (HPV4). HPV4 was licensed for use in males in October 2009, and ACIP issued a permissive recommendation for use in males. Introductory sentences were added to the footnotes for measles, mumps, rubella, influenza, pneumococcal, hepatitis

## Changes for 2010

### Footnotes (Figures 1 and 2)

- The human papillomavirus (HPV) footnote (#2) includes language that a bivalent HPV vaccine (HPV2) has been licensed for use in females. Either HPV2 or the quadrivalent human papillomavirus vaccine (HPV4) can be used for vaccination of females aged 19 through 26 years. In addition, language has been added to indicate that ACIP issued a permissive recommendation for use of HPV4 in males.
- The measles, mumps, rubella (MMR) footnote (#5) has language added to clarify which adults born during or after 1957 do not need 1 or more doses of MMR vaccine for the

# New and Revised ACIP Recommendations

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- 4-dose rabies vaccine schedule

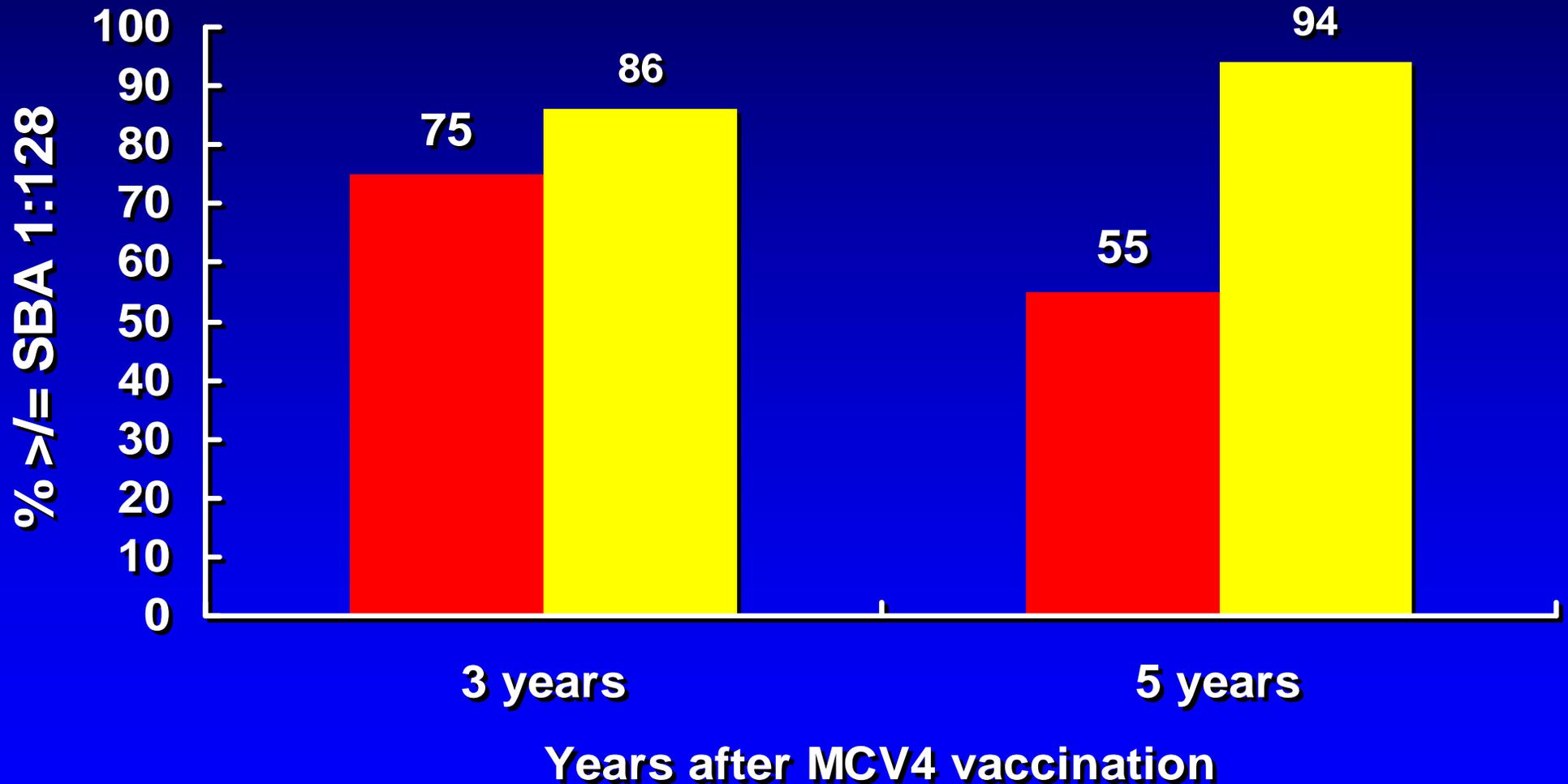
# 2005 Meningococcal ACIP Statement: Revaccination after MCV4

- In its 2005 recommendations for MCV4, ACIP made no recommendation about revaccination pending the availability of additional data
- Serologic data are now available from the manufacturer that show significant decline in antibody 3-5 years after vaccination although few “breakthrough” cases have been reported

*MMWR 2005;54(RR-7)*

# Seroprotection Rates Following MCV4 Vaccination

■ C ■ Y



sanofi pasteur unpublished data, 2009

# MCV4 Revaccination Recommendations

- Children through age 18 years who received their **first dose of MCV4 or MPSV4 at ages 2 through 6 years** and remain at increased risk for meningococcal disease should receive an additional dose of MCV4 **three years** after their first dose\*

\*off-label recommendation. *MMWR* 2009;58(No. 37)

# MCV4 Revaccination Recommendations

- Persons through age 55 years who received a dose of MCV4 or MPSV4 after age 6 years and remain at increased risk for meningococcal disease should receive an additional dose of MCV4 five years after their previous dose\*

\*off-label recommendation. *MMWR* 2009;58(No. 37)

# MCV4 Revaccination Recommendations

- High-risk persons who should be revaccinated\* with MCV4:
  - persistent complement component deficiency
  - anatomic or functional asplenia
  - Microbiologists with prolonged exposure to *Neisseria meningitidis*
  - frequent travelers to or persons living in areas with high rates of meningococcal disease

\*off-label recommendation. *MMWR* 2009;58(No. 37)

# MCV4 Revaccination Recommendations

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- **MCV4 revaccination is NOT recommended for persons whose only risk factor is living in on-campus housing (i.e., college student living in a dormitory)**

*MMWR* 2009;58(No. 37)

## Updated Recommendation from the Advisory Committee on Immunization Practices (ACIP) for Revaccination of Persons at Prolonged Increased Risk for Meningococcal Disease

The Advisory Committee on Immunization Practices (ACIP) recommends quadrivalent meningococcal conjugate vaccine, (MCV4) (Menactra, Sanofi Pasteur, Swiftwater, Pennsylvania) for all persons aged 11–18 years and for persons aged 2–55 years at increased risk for meningococcal disease (1–3). MCV4 is licensed as a single dose. Because of the high risk for meningococcal disease among certain groups and limited data on duration of protection, at its June 2009 meeting ACIP recommended that persons previously vaccinated with either MCV4 or MPSV4 (Menomune, Sanofi Pasteur) who are at prolonged increased risk for meningococcal disease should be revaccinated with MCV4. Persons who previously were vaccinated at age  $\geq 7$  years and are at prolonged increased risk should be revaccinated

subsets of subjects from the MCV4 prelicensure clinical trial were revaccinated 3 years ( $n = 76$ ) and 5 years ( $n = 134$ ) after receiving MCV4. Of 71 persons aged 11–18 years at primary vaccination who had been vaccinated with MCV4 3 years previously, 75% and 86% had SBA titers greater than 1:128 for serogroups C and Y, respectively, before revaccination. Of 108 persons aged 2–10 years at primary vaccination who had been vaccinated with MCV4 5 years previously, 55% and 94% had SBA titers greater than 1:128 for serogroups C and Y, respectively, before revaccination. All persons revaccinated with MCV4 in these studies achieved SBA titers greater than 1:128 for serogroups C and Y. Approximately 50%–70% of persons in both the previously vaccinated ( $n = 210$ ) and vaccine naive groups ( $n = 323$ ) reported mild to moderate local and systemic adverse events after revaccination (or initial vaccination) with MCV4. However, no serious adverse events were reported in either group (Sanofi Pasteur, unpublished data, 2009).

On the basis of these data, expert opinion of the workgroup members, and feedback from partner organizations, the workgroup proposed that persons at prolonged increased risk for meningococcal disease be revaccinated with MCV4. ACIP approved this proposal at its June 24, 2009, meeting. Persons

# New and Revised ACIP Recommendations

- 2010 immunization schedules
- Meningococcal conjugate revaccination
- **HPV2 and HPV4 for males**
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- 4-dose rabies vaccine schedule

# HPV Vaccines

- **HPV4 (Gardasil, Merck)**
  - contains HPV types 16, 18, 6 and 11
  - approved for the prevention of cervical, vaginal and vulvar cancers (in females) and genital warts (in females and males)
- **HPV2 (Cervarix, GSK)**
  - contains HPV types 16 and 18
  - approved for the prevention of cervical cancers in females

# HPV Vaccine Recommendations\*

- HPV4 or HPV2 is recommended for the prevention of cervical precancers and cancers in females
- HPV4 is recommended for the prevention of cervical, vaginal and vulvar precancers and cancers and genital warts in females
- Administer the first dose to females at age 11 or 12 years

\*ACIP provisional recommendations, October 2009

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# HPV Vaccine Recommendations\*

- Administer the series to females at age 13 through 18 years if not previously vaccinated
- HPV4 may be administered in a 3-dose series to males aged 9 through 18 years to reduce their likelihood of acquiring genital warts

\*ACIP provisional recommendations, October 2009

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# New and Revised ACIP Recommendations

- 2010 immunization schedules
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- **PCV13**
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- Japanese Encephalitis vaccines
- 4-dose rabies vaccine schedule

# 13-Valent Pneumococcal Conjugate Vaccine (PCV13)

- **Licensed by FDA**      **February 24, 2010**
- **Recommendations for use approved by ACIP**      **February 24, 2010**
- **Recommendations published by MMWR**      **March 12, 2010**

***MMWR* 2010;59(No. 6):258-61**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# PCV13

- Contains the same serotypes of *S. pneumoniae* as PCV7 plus serotypes 1, 3, 5, 6A, 7F, and 19A conjugated to nontoxic diphtheria CRM<sub>157</sub> carrier protein
- Each dose contains 0.125 mg of aluminum phosphate adjuvant
- No preservative or latex
- Approved by FDA for use among children 6 weeks through 71 months of age

**MMWR 2010;59(No. 6):258-61**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# ACIP Recommendations for PCV13

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- **Routine vaccination recommendation the same as for PCV7**
  - all children 2 through 59 months of age
  - 4 doses at 2, 4, 6, and 12 to 15 months
  - fewer doses if series started at 7 months of age or older
- **Children who have received 1 or more doses of PCV7 should complete the immunization series with PCV13**

***MMWR 2010;59(No. 6):258-61***

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

TABLE 2. Recommended routine vaccination schedule for 13-valent pneumococcal conjugate vaccine (PCV13) among infants and children who have not received previous doses of 7-valent vaccine (PCV7) or PCV13, by age at first dose — Advisory Committee on Immunization Practices (ACIP), United States, 2010

Age at first dose (mos)	Primary PCV13 series*	PCV13 booster dose†
2–6	3 doses	1 dose at age 12–15 mos
7–11	2 doses	1 dose at age 12–15 mos
12–23	2 doses	—
24–59 (Healthy children)	1 dose	—
24–71 (Children with certain chronic diseases or immunocompromising conditions§)	2 doses	—

\* Minimum interval between doses is 8 weeks except for children vaccinated at age <12 months for whom minimum interval between doses is 4 weeks. Minimum age for administration of first dose is 6 weeks.

† Given at least 8 weeks after the previous dose.

§ For complete list of conditions, see Table 1.

# ACIP Recommendations for PCV13

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- **Minimum age 6 weeks**
- **Minimum intervals**
  - **4 weeks between doses 1 and 2 and doses 2 and 3**
  - **8 weeks between next-to-last and last doses**

***MMWR* 2010;59(No. 6):258-61**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# ACIP Recommendations for PCV13 Supplemental Dose

- A single supplemental dose of PCV13 is recommended for children who have received a complete age-appropriate series of PCV7
  - healthy children 14 through 59 months
  - children with an underlying medical condition 14 through 71 months (including those who have already received a dose of PPSV)

*MMWR* 2010;59(No. 6):258-61

TABLE 1. Underlying medical conditions that are indications for pneumococcal vaccination among children, by risk group — Advisory Committee on Immunization Practices (ACIP), United States, 2010

Risk group	Condition
Immunocompetent children	Chronic heart disease* Chronic lung disease† Diabetes mellitus Cerebrospinal fluid leaks Cochlear implant
Children with functional or anatomic asplenia	Sickle cell disease and other hemoglobinopathies Congenital or acquired asplenia, or splenic dysfunction
Children with immunocompromising conditions	HIV infection Chronic renal failure and nephrotic syndrome Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation Congenital immunodeficiency§

\* Particularly cyanotic congenital heart disease and cardiac failure.

† Including asthma if treated with prolonged high-dose oral corticosteroids.

§ Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).

# ACIP Recommendations for PCV13 Supplemental Dose

- A single supplemental dose of PCV13 may be administered to children 6 through 18 years of age who are at increased risk for invasive pneumococcal disease\*
  - sickle cell disease
  - HIV infection and other immunocompromising conditions
  - cochlear implant
  - CSF leak

\*off-label recommendation

*MMWR* 2010;59(No. 6):258-61

# ACIP Recommendations for PCV13

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- When PCV13 is available it should be used when indicated
- If PCV13 is not available then PCV7 should be used (i.e., do not defer pneumococcal vaccination if PCV13 is not available)

**MMWR 2010;59(No. 6):258-61**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# ACIP Recommendations for PCV13

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- **Do not discard your remaining supply of PCV7**
  - **Private supplies of PCV7 may be returned to the manufacturer**
  - **Contact state or local immunization program regarding unused supply of PCV7**

**MMWR 2010;59(No. 6):258-61**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

## Licensure of a 13-Valent Pneumococcal Conjugate Vaccine (PCV13) and Recommendations for Use Among Children — Advisory Committee on Immunization Practices (ACIP), 2010

On February 24, 2010, a 13-valent pneumococcal conjugate vaccine (PCV13 [Pevnar 13, Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.]) was licensed by the Food and Drug Administration (FDA) for prevention of invasive pneumococcal disease (IPD) caused by the 13 pneumococcal serotypes covered by the vaccine and for prevention of otitis media caused by serotypes in the 7-valent pneumococcal conjugate vaccine formulation (PCV7 [Pevnar, Wyeth]). PCV13 is approved for use among children aged 6 weeks–71 months and succeeds PCV7, which was licensed by FDA in 2000. The Pneumococcal Vaccines Work Group of the Advisory Committee on Immunization Practices (ACIP) reviewed available data on the immunogenicity, safety, and cost-effectiveness of PCV13, and on estimates of the vaccine-preventable pneumococcal disease burden.

PCV13 is administered intramuscularly and is available in single-dose, prefilled syringes that do not contain latex (2).

**Immunogenicity profile.** The immunogenicity of PCV13 was evaluated in a randomized, double-blind, active-controlled trial in which 663 U.S. infants received at least 1 dose of PCV13 or PCV7 (3). To compare PCV13 antibody responses with those for PCV7, criteria for noninferior immunogenicity after 3 and 4 doses of PCV13 (pneumococcal immunoglobulin G [IgG] antibody concentrations measured by enzyme immunoassay) were defined for the seven serotypes common to PCV7 and PCV13 (4, 6B, 9V, 14, 18C, 19F, and 23F) and for the six additional serotypes in PCV13 (serotypes 1, 3, 5, 6A, 7F, and 19A). Functional antibody responses were measured by opsonophagocytosis assay (OPA) in a subset of the

# New and Revised ACIP Recommendations

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# Influenza Vaccine Recommendations for the 2010-2011 Season

- On February 24, 2010, ACIP unanimously approved a revision for the 2010-2011 influenza season
- Influenza vaccination recommendations for adults were expanded to include all adults beginning in the 2010-11 influenza season
- All people age 6 months and older are now recommended to receive annual influenza vaccination

ACIP provisional recommendation, February 24, 2010

# New and Revised ACIP Recommendations

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- HPV2 and HPV4 for males
- PCV13
- Influenza
- Age and interval for the last dose of IPV
- Japanese Encephalitis vaccines
- 4-dose rabies vaccine schedule

# New IPV Recommendations

- No change in the routine IPV schedule of four doses at ages 2 months, 4 months, 6 through 18 months, and 4 through 6 years
- Minimum interval between the next-to-last and last doses is now 6 months
- Minimum age for the final IPV dose is now 4 years

*MMWR* 2009;58(No. 30):829-30

TABLE 2. Limits of detection of Madin-Darby canine kidney (MDCK)-grown influenza A/California/4/2009 (H1N1) for three rapid influenza diagnostic tests (RIDTs), by selected measurement values — United States, 2009

RIDT	Values		
	Lowest dilution with positive result	TCID <sub>50</sub> /mL <sup>†</sup>	Ct <sup>†</sup>
BinaxNOW Influenza A&B	10 <sup>-2</sup>	10 <sup>5.5</sup>	22.15
Directigen EZ Flu A+B	10 <sup>-3</sup>	10 <sup>4.5</sup>	26.05
QuickVue A+B	10 <sup>-3</sup>	10 <sup>4.5</sup>	26.05

\* TCID<sub>50</sub> = 50% tissue culture infectious dose.

† Ct (cycle threshold) values reported as an average of three reactions each of duplicate dilution series.

grown in MDCK cells should be viewed with caution, because Ct limit of detection values for cultured viruses can vary with the virus strain, its passage history, and the substrate used for propagation (e.g., MDCK cells or chicken embryos). Optimizing specimen collection, transportation, and testing practices to ensure that specimens have the highest amount of virus possible would be expected to increase the likelihood of detecting influenza virus, when present, using RIDTs and other diagnostic tests.

The results described in this report should be viewed as preliminary. More data are needed on the clinical performance of all RIDTs to detect novel influenza A (H1N1) virus in

## Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Routine Poliovirus Vaccination

This report updates Advisory Committee on Immunization Practices (ACIP) recommendations for routine poliovirus vaccination. These updates aim to 1) emphasize the importance of the booster dose at age  $\geq 4$  years, 2) extend the minimum interval from dose 3 to dose 4 from 4 weeks to 6 months, 3) add a precaution for the use of minimum intervals in the first 6 months of life, and 4) clarify the poliovirus vaccination schedule when specific combination vaccines are used.

On June 17, 1999, ACIP recommended that all poliovirus vaccine administered in the United States be an inactivated poliovirus vaccine (IPV) beginning January 1, 2000. This policy was implemented to eliminate the risk for vaccine-associated paralytic poliomyelitis, a rare condition that has been associated with use of the live oral poliovirus vaccine (OPV). Since 1999, no OPV has been distributed in the United States. Under these ACIP recommendations, the routine IPV vaccination schedule in the United States consists of 4 doses administered at ages 2 months, 4 months, 6–18 months, and



**MMWR**<sup>TM</sup>

**Morbidity and Mortality Weekly Report**

[www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

Recommendations and Reports

March 12, 2010 / Vol. 59 / No. RR-1

## **Japanese Encephalitis Vaccines**

**Recommendations of the Advisory Committee on  
Immunization Practices (ACIP)**



# MMWR<sup>TM</sup>

**Morbidity and Mortality Weekly Report**

[www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

Recommendations and Reports

March 19, 2010 / Vol. 59 / No. RR-2

## **Use of a Reduced (4-Dose) Vaccine Schedule for Postexposure Prophylaxis to Prevent Human Rabies**

**Recommendations of the Advisory Committee  
on Immunization Practices**

# Menveo MCV4 Vaccine

- **Approved by FDA on February 19, 2010 for persons 11 through 55 years of age**
- **Lyophilized serogroup A vaccine reconstituted with liquid containing serogroups C, Y, and W135**
- **May be used for any person 11 through 55 years of age for whom MCV4 is indicated**



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# This is an official **CDC HEALTH ADVISORY**

Distributed via Health Alert Network

Monday, March 22, 2010, 15:54 EDT (03:54 PM EDT)

CDCHAN-00311-2010-03-22-ADV-N

## **Recommendation to Temporarily Suspend Usage of GlaxoSmithKline Rotarix (Rotavirus) Vaccine**

**Summary:** The U.S. Food and Drug Administration (FDA) has learned that DNA from porcine circovirus type 1 (PCV1), a virus not known to cause disease in humans, is present in the Rotarix vaccine. All available evidence indicates that there has been no increased risk to patients who have received this vaccine. PCV1 is not known to cause any disease in animals or humans; therefore, it has not been routinely tested for in vaccine development. Rotarix has been extensively studied, before and after approval, and found to have an excellent safety record (i.e., no unusual adverse events). However, FDA is recommending that healthcare practitioners temporarily suspend usage of the Rotarix vaccine for rotavirus immunization in the United States while the agency learns more about the detection of components of

# Suspension of Usage of Rotarix

- On March 22, 2010 the FDA recommended temporary suspension of usage of Rotarix rotavirus vaccine
- DNA from porcine circovirus type 1 (PCV1) virus was identified in both finished Rotarix and in the cell bank and seed virus
- PCV1 is not known to cause any disease in animals or humans
- No specific actions are recommended for children who received Rotarix

# CDC Vaccines and Immunization

## Contact Information

- **Telephone**      **800.CDC.INFO**  
(for patients and parents)
- **Email**              **nipinfo@cdc.gov**  
(for providers)
- **Website**            **www.cdc.gov/vaccines/**
- **Vaccine Safety**   **www.cdc.gov/vaccinesafety/**