



ACIP
Briefing Documents

February 2007



February 7, 2006

Julie Louise Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Mailstop D14
Atlanta, GA 30333

Dear Julie,

Attached are briefing documents for the following topics that will be discussed during the ACIP meeting on February 21-22, 2007. Presentation of data in these documents is standardized for each topic for ease of reference. We have added presentations at each meeting on the status of immunization safety as well as status of supply for each of the newly approved vaccines. These presentations will emphasize the fact that CDC is interested in and is monitoring immunization safety. Updates on vaccine supply will assist with implementation of immunization programs. These documents were prepared with the cooperation and collaboration of many people.

topics

Hepatitis A Post-Exposure Prophylaxis*
Rotavirus
Influenza vaccine*
HPV vaccine
*vote to be taken

main preparers

Beth Bell
Umesh Parashar
Anthony Fiore
Laurie Markowitz

Other topics that will be discussed but for which documents are not included are the following:

1. Thimerosal: reviewing the evidence
2. Immunization safety
3. The Hib component of a combination DTaP/IPV/Hib vaccine
4. Vaccine supply - update
5. Agency updates

The following information also is enclosed.

- A. List of ACIP members and liaison organizations
- B. Draft meeting agenda (www.cdc.gov/nip/acip)
- C. Provisional recommendations of the ACIP

Minutes of the October 25-26, 2006 ACIP meeting can be found at www.cdc.gov/nip/acip/minutes.htm

If you need additional information, please contact me or any of the people listed above. We hope that you will find this material useful.

Sincerely,

Larry K. Pickering, M.D., F.A.A.P.
Senior Advisor to the Director
National Center for Immunization and Respiratory Diseases
Executive Secretary
Advisory Committee on Immunization Practices

LKP/srr
enclosures

DRAFT - FEB 8, 2007

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention
1600 Clifton Road, NE, Tom Harkin Global Communications Center (Building 19), Atlanta, Georgia
February 21-22, 2007

	<u>AGENDA ITEM</u>	<u>PURPOSE</u>	<u>PRESIDER/PRESENTER(S)</u>
Wednesday February 21			
8:00	Welcome & introductions		Dr. Jon Abramson (Chair, ACIP) Dr. Larry Pickering (Executive Secretary, ACIP; CDC/OD)
8:30	<u>Hepatitis A Post-Exposure Prophylaxis</u> Use of hepatitis A vaccine for post-exposure prophylaxis	Information Discussion	Dr. Beth Bell (CDC/NCHHSTP) Dr. John Victor, Ph.D. (Dept of Epidemiology, School of Public Health, University of Michigan)
	VFC resolution	Vote VFC Vote	Dr. Greg Wallace (CDC/NCIRD)
9:40	<u>Rotavirus Vaccine</u> General Update	Information	Dr. Umesh Parashar (CDC/NCIRD)
9:45	Update on disease burden data and vaccine effectiveness monitoring	Information	Dr. Daniel Payne (CDC/NCIRD)
9:55	Update on adverse event monitoring and risk assessment	Information	Dr. Manish Patel (CDC/NCIRD) Ms. Penina Haber (CDC/ISO)
10:25	<i>Break</i>		
10:55	<u>Thimerosal: Reviewing the Evidence</u>	Information Discussion	Dr. Jay Lieberman (Pediatric Infectious Diseases, University of California, Irvine)
11:45	<u>Vaccine Supply</u> Update on vaccine supply	Information	Dr. Greg Wallace (CDC/NCIRD)
12:15	<i>Lunch</i>		
1:15	<u>Influenza</u> Update: seasonal influenza epidemiology, virologic surveillance and antiviral drug resistance	Information & Discussion	Dr. Ban Mishu Allos (ACIP, Influenza Workgroup Chair) & Dr. Anthony Fiore (CDC/NCIRD)
1:35	Update on influenza vaccine supply	Information	"
1:45	2007 influenza vaccination recommendations	Information & Discussion	Dr. Anthony Fiore (CDC/NCIRD)
2:45	Public comment		
3:00	2007 influenza vaccination recommendations	Vote	Dr. Anthony Fiore (CDC/NCIRD)
3:15	<i>Break</i>		
3:45	VFC resolution on influenza vaccine recommendations	Information Discussion VFC Vote	Dr. Greg Wallace (CDC/NCIRD)
4:00	Interagency pandemic influenza vaccine prioritization workgroup update	Information	Dr. Ben Schwartz (NVPO)
4:30	Review of safety data on FluMist® (Influenza Vaccine Virus Live, Intranasal)	Information Discussion	Dr. Robert Walker (MD, Vice President, Clinical Development, MedImmune)
5:30	Public comment		
5:45	Adjourn		

	<u>AGENDA ITEM</u>	<u>PURPOSE</u>	<u>PRESIDER/PRESENTER(S)</u>
Thursday February 22			
8:00	Unfinished Business		Jon Abramson (Chair, ACIP)
8:30	<u>Haemophilus influenzae Type b [Hib]</u> Introduction	Information	Nancy Rosenstein Messonnier (CDC/NCIRD)
	Review of data regarding use of Hib-containing vaccines	Information & Discussion	George Carlone, M. Patricia Joyce, Sandra Steiner (CDC/NCIRD)
9:30	<u>Immunization Safety Office</u> Study and surveillance updates	Information	Dr. Robert Davis (CDC/ISO) & Dr. John Iskander (CDC/ISO)
10:30	<i>Break</i>		
11:00	<u>Human Papillomavirus (HPV) Vaccine</u> Introduction	Information	Dr. Janet Gilsdorf (ACIP, HPV Vaccine Workgroup Chair)
	Quadrivalent HPV vaccine	Information Discussion	Dr. Eliav Barr (Merck)
11:25	Bivalent HPV vaccine	Information Discussion	Dr. Gary Dubin (GlaxoSmithKline [GSK])
11:50	General update	Information Discussion	HPV Vaccine ACIP Workgroup
12:10	<u>Agency Updates (CDC/CCID/NCIRD, CMS, DOD, DVA, FDA, HRSA, IHS, NIH, NVPO)</u>	Information	Agency Representatives
12:40	Public Comment		
12:55	Adjourn		

Acronyms

ACIP	Advisory Committee on Immunization Practices
CCID	Coordinating Center for Infectious Diseases (proposed)
CDC	Centers for Disease Control & Prevention
CISA	Clinical Immunization Safety Assessment
CMS	Centers for Medicare and Medicaid Services
DOD	Department of Defense
DVA	Department of Veterans Affairs
DVD	Division of Viral Diseases [of NCIRD] (proposed)
FDA	Food and Drug Administration
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
ISO	Immunization Safety Office (of CDC/OD/Office of the Chief Science Officer)
NCHHSTP	National Center for HIV, Hepatitis, STD and TB Prevention [of CDC/CCID] (proposed)
NCIRD	CDC National Center for Immunization & Respiratory Diseases [of CDC/CCID] (proposed)
NCPDCID	National Center for Preparedness, Detection, and Control of Infectious Diseases (proposed)
NCZVED	National Center for Zoonotic, Vector-Borne, and Enteric Diseases [of CDC/CCID] (proposed)
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
OD	Office of the Director [of CDC]
VSD	Vaccine Safety Datalink

Briefing Documents

- Hepatitis A post-exposure prophylaxis**
- Rotavirus vaccine**
- Influenza vaccine**
- HPV vaccine**

Hepatitis A Vaccine

1. Topic: Post-exposure prophylaxis with hepatitis A vaccine

A recommendation to allow for the option of using hepatitis A vaccine instead of immune globulin (IG) after exposure to hepatitis A virus (HAV)

2. Statement of current status and key issues: In 1995, highly effective inactivated hepatitis A vaccines were first licensed in the United States for persons ≥ 2 years of age. In 2005, the vaccine manufacturers received FDA approval for use of the vaccines in children 12-23 months of age.

In 1996, 1999 and 2006 the ACIP made recommendations for use of hepatitis A vaccine. Currently, the ACIP recommends hepatitis A vaccination of all children at 12-23 months of age, catch-up vaccination of older children in selected geographic areas, and vaccination of persons at increased risk (e.g., travelers to endemic areas, users of illicit drugs, men who have sex with men).

For many years, IG has been recommended for prophylaxis following exposure to HAV. When administered within 2 weeks of last exposure, IG is 80%-90% effective in preventing clinical hepatitis A. IG is recommended for close personal contacts of hepatitis A cases and in selected circumstances after hepatitis A is recognized in a food handler or a child care center. Despite limited data suggesting that hepatitis A vaccine might be efficacious when administered after exposure, in the absence of an appropriately designed clinical trial comparing the postexposure efficacy of vaccine with that of IG, the ACIP has continued to recommend IG exclusively in these settings. However, for a number of years other countries (e.g., Canada, Italy) have recommended hepatitis A vaccine rather than IG for postexposure prophylaxis, based on these limited data.

A CDC-funded randomized, double-blinded noninferiority clinical trial has now been completed. The trial compared the post-exposure efficacy of IG and hepatitis A vaccine in preventing symptomatic hepatitis A when given within 14 days after exposure. The study was conducted in Almaty, Kazakhstan among 1090 household contacts (most of whom were 2-40 years of age) of hepatitis A cases. Symptomatic hepatitis A was confirmed in 25 contacts who had received vaccine (4.4%) and 17 contacts who received IG (3.3%) [relative risk 1.35; upper bound 95% confidence interval 2.4], meeting the pre-specified criterion for noninferiority of vaccine to IG. This criterion required that the 95% confidence interval of the upper bound of the relative risk be no greater than 3. Under the assumption of 90% IG efficacy, the point estimate for hepatitis A vaccine efficacy in preventing the primary endpoint (symptomatic hepatitis A infection) was 86%. Among the several secondary endpoints examined, the risk of hepatitis A in the vaccine group was never more than 1.5% greater than that in the IG group.

3. Background: In the pre-vaccine era, an average of 26,000 hepatitis A cases were reported annually in the United States. Since 2000, hepatitis A rates have declined dramatically, as ACIP recommendations for hepatitis A vaccination of children have been implemented. The 2005 rate of 1.5/100,000 (4,488 cases) is the lowest ever reported in 40 years of surveillance; the provisional 2006 rate is yet lower. Nonetheless, the need for postexposure prophylaxis remains, both for close personal contacts of hepatitis A cases and in the context of exposure

to infected foodhandlers. Although the overall number of IG doses used for post-exposure prophylaxis is unknown, provision of IG to patrons of restaurants exposed to an infected foodhandler can sometimes involve thousands of individuals.

4. Reason topic is being presented to ACIP: The information is being presented for discussion, a vote, and a VFC vote.

In the absence of a clinical trial directly comparing the postexposure efficacy of IG and hepatitis A vaccine, the ACIP continued to recommend IG in the postexposure setting. The results of an appropriately designed and conducted clinical trial are now available, and indicate that the postexposure efficacy of IG and hepatitis A vaccine are similar. Hepatitis A vaccine offers a number of advantages over IG, including long term protection, ease of administration, acceptability and availability, and the cost per dose is similar to IG. Given that the data deemed necessary by ACIP to consider a recommendation for hepatitis A vaccine postexposure are now available, it is appropriate to present these data to ACIP and ask for a vote.

Even with the completion of this randomized trial, available data remain insufficient for FDA licensure of the vaccines for this indication. Therefore, hepatitis A vaccine after exposure represents off-label use. FDA is familiar with recent data and aware of ACIP's deliberations. It is highly unlikely that the kind of additional studies that would be required by FDA to license the vaccine for this indication could ever be done, especially in view of the current very low hepatitis A rates. Therefore, currently available data are likely to continue to be the only available data, and are strong enough to support the proposed recommendation.

5. Policy options: Policy options include making a recommendation that hepatitis A vaccine or IG can be used for prophylaxis after exposure to HAV (recognizing the limitations of available data) or leaving in place the current recommendation for use of IG alone.

6. Recommendations of the ACIP Workgroup/CDC staff: The hepatitis vaccines workgroup is not currently active. CDC staff members recommend that the ACIP approve a recommendation that hepatitis A vaccine or IG can be used for postexposure prophylaxis, as well as acknowledging recognition of the limitations of the available data regarding hepatitis A vaccine efficacy in this setting. For example, no data are available for populations not included in the efficacy study (e.g., among persons > 40 years of age, persons with certain medical conditions).

7. Implications of ACIP action: The ability to use hepatitis A vaccine for postexposure prophylaxis would provide a number of public health benefits. Because of hepatitis A vaccine's advantages over IG, at a minimum this recommendation will simplify the provision of postexposure prophylaxis and provide long term protection to exposed individuals. It is also possible that the availability and ease of administration of hepatitis A vaccine will increase the number of exposed individuals who receive prophylaxis. The recommendation would bring U.S. policy in line with that of Canada and European countries.

Rotavirus Vaccine

1. Topic: Update on Rotavirus Vaccination

2. Statement of key issues: In February 2006, the ACIP recommended immunization of all US infants with a newly licensed bovine-human reassortant rotavirus vaccine (Rotateq™) developed by Merck and Co. GlaxoSmithKline (GSK) is developing another rotavirus vaccine that has completed successful phase III safety and efficacy studies, primarily in countries of Latin America. GSK has not announced plans to seek licensure in the United States.

3. Background (morbidity and mortality, trends): Rotavirus infection is the leading cause of severe diarrhea in infants and young children. Worldwide, rotavirus causes ~500,000 deaths and millions of hospitalizations each year in children under 5 years of age. In the United States, rotavirus disease occurs in annual winter epidemics and causes about 20-60 deaths, >50,000 hospitalizations, >550,000 emergency department or outpatient visits, and leads to approximately \$1 billion of health care and lost-productivity costs each year.

4. Reason topic presented to ACIP: Presentations at the February 2007 meeting are for information only and will update ACIP members on vaccine uptake and ongoing activities to monitor safety and effectiveness of vaccination. Data on monitoring of intussusception reports following vaccination will be described in detail, because an earlier rotavirus vaccine (Rotashield™) withdrawn in 1998 was associated with this adverse event. To date, available data do not suggest an increased risk of intussusception following Rotateq™ vaccination, but the data need to be interpreted with many caveats and continued monitoring is important.

5. Policy options if applicable: N/A.

6. Recommendations of ACIP workgroup/CDC staff: N/A.

7. Implications of ACIP action: N/A.

Influenza Vaccine

1. **Topic:** Influenza vaccine

2. **Key issues:** Annual seasonal influenza prevention and control recommendations and VFC vote.

- a) Information from manufacturers regarding projected vaccine supply for 2007-2008 influenza season, including the number of doses for adults and for children, and the status of preservatives in influenza vaccines.
- b) Report from the Interagency Working Group on Pandemic Influenza Vaccine Prioritization (presented by NVPO/Ben Schwartz)
- c) Safety data presented by MedImmune regarding use of cold-adapted influenza vaccine (CAIV-T, also known as LAIV; trade name FluMist[®]) in children < 5 years old.

3. **Background:**

- a) Preliminary antiviral resistance data from analysis of 2006-2007 influenza virus isolates indicates that neuraminidase inhibitors (oseltamivir or zanamivir) should be preferentially used for treatment or prophylaxis, and that resistance to neuraminidase inhibitors remains rare.
- b) Children ≥ 6 months through <9 years of age who received only one dose in their first year of vaccination are now recommended to receive two doses in their second year of vaccination. Previously these children were recommended to receive only one dose in their second year of vaccination. This change harmonizes with new recommendations from the AAP.
- c) The recommendations for vaccine strains will be made at the FDA's February 27-28, 2007 VRBPAC meeting.
- d) Plans for consideration of expansion of routine influenza vaccination recommendations to include school age children will be discussed. The ACIP Influenza Vaccine Workgroup continues to gather information regarding vaccine safety and effectiveness, adequacy of supply, and feasibility of expanding recommendations to include school-aged children, possibly as early as 2008. The Workgroup is convening a meeting in summer or fall 2007 that will include scientists, vaccine manufacturers, public health officials and stakeholders.
- e) The manufacturer of CAIV-T (MedImmune) has submitted a BLA that, if approved by FDA, would allow CAIV-T to be used in children > 12 months of age without a history of wheezing rather than restricting use to the currently approved use in children >5 years old.

4. **Reason topic is being presented to ACIP**

- a) ACIP requested updated surveillance and antiviral resistance information.
- b) Vote is required to approve recommendations, including change in recommendations for children who only receive one dose of vaccine in their first year of vaccination.
- c) Vaccine supply continues to be of interest, particularly plans to increase availability of preservative-free vaccine.

- d) The ACIP needs to be updated on plans for expansion of vaccination recommendations.
- e) ACIP requested update on activities of the Interagency Working Group on Pandemic Influenza Vaccine Prioritization.
- f) ACIP requested presentation of CAIV-T safety data in young children in preparation for possible early summer 2007 FDA licensure for use in younger children.

5. Policy considerations

- a) Change in recommendations for children ≥ 6 months to < 9 years of age who received only one vaccine dose in their first year of vaccination will harmonize ACIP recommendations with recommendations of AAP.
- b) Interagency Working Group pandemic vaccine prioritization recommendations might differ from previously published ACIP/NVAC recommendations (approved in 2005).

6. Recommendations of ACIP Workgroup

- a) Children who only received one dose in their first year of influenza vaccination should receive two doses in their second year of vaccination.
- b) Approve 2007-2008 influenza vaccine recommendations

7. Implications of ACIP action

- a) Approved influenza vaccine recommendations for the 2007-08 influenza season.
- b) Change in recommendations for children ≥ 6 months to < 9 years of age who received only one vaccine dose in first year of influenza vaccination.

Human Papillomavirus (HPV) Vaccine

1. **Topic:** Human Papillomavirus Vaccine

2. Statement of issue: The quadrivalent (types 6,11,16,18) HPV vaccine, produced by Merck & Co, Inc. was licensed by FDA in June 2006 for use in females 9-26 years of age. In June 2006, this vaccine was recommended by ACIP for routine immunization of 11-12 year-old females. Catch-up vaccination was recommended for 13-26 year-old females. A bivalent HPV vaccine (types 16,18) is being developed by GlaxoSmithKline (GSK). GSK has announced they will submit a biologic license application to FDA in April 2007. Two HPV vaccines could be available in the US by 2007 or 2008.

3. Background: Genital HPV infections are estimated to be the most common sexually transmitted infection in the United States, with an estimated 6.2 million persons becoming newly infected every year. It is estimated that 50% of sexually active women and men will acquire more one or more genital HPV types during their lifetime. Although majority of infections cause no symptoms and are self-limited, genital HPV is of public health concern because persistent infection with certain types can cause cervical cancer in women as well as other anogenital cancers in both men and women. Genital HPV infections are categorized according to their association with cervical cancer. Infections with low-risk types (such as types 6 and 11) can cause low-grade cervical cell abnormalities and genital warts. Infection with high-risk types (such as types 16 and 18) can cause low and high-grade cervical cell abnormalities, and genital cancers. HPV 16 and 18 are responsible for about 70% of cervical cancer cases, and HPV types 6 and 11 are responsible for about 90% of genital warts.

Both the quadrivalent and bivalent HPV vaccines are composed of viral-like particles (VLP). The quadrivalent vaccine contains VLPs to HPV types 6,11,16,18; the bivalent vaccine contains VLPs to HPV types 16,18. The GSK vaccine contains a proprietary adjuvant (ASO4), which is not in any licensed vaccine in the US. The clinical development programs of the two companies are similar, but the Merck program includes males and females, while the GSK program is focused on females. There are some data from the bivalent HPV vaccine phase II study indicating it may provide cross protection against other oncogenic HPV types, in addition to types 16 and 18. Both Merck and GSK are conducting bridging immunogenicity and efficacy studies in women older than 26 years of age. Merck also is conducting efficacy studies in men. Thus, data from both the initial license application from GSK and new data from the Merck vaccine trials will be available over the next 1 to 2 years; additional issues and recommendations will need to be considered by ACIP.

4. Reason topic to be presented to ACIP: No vote will occur at this meeting. Information is being presented to keep ACIP abreast of developments with HPV vaccines and to build a knowledge base for future meetings when a vote on the GSK bivalent HPV vaccine is anticipated.

Three presentations will be made at this meeting:

- Quadrivalent HPV vaccine - update from the phase III vaccine efficacy trials, with data through 36 months of follow-up (Merck).
- Bivalent HPV vaccine - clinical development program and phase II efficacy/safety data (GSK).
- Update on HPV vaccine, including a brief overview of various topics including vaccine distribution, safety monitoring and impact monitoring (ACIP HPV vaccine workgroup).

5. Policy Options: Not applicable.

6. Recommendation of ACIP workgroup/CDC staff: Not applicable

7. Implications of action: No specific action is anticipated at the February 2007 ACIP meeting.



ACIP Members,
Ex Officio Members,
and Liaison
Organization
Representatives

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
JULY 2006

CHAIRMAN

ABRAMSON, Jon S., M.D.
Weston M. Kelsey Professor and Chair
Department of Pediatrics
Wake Forest University School of Medicine
Winston-Salem, North Carolina
TERM: 07/01/05-06/30/07

EXECUTIVE SECRETARY

PICKERING, Larry K., M.D.
Senior Advisor to the Director
National Immunization Program
Centers for Disease Control and
Prevention
1600 Clifton Road, NE
Mailstop E-05
Atlanta, Georgia 30333
404-639-8200
FAX: 404-639-8626

MEMBERS

ALLOS, Ban Mishu, M.D.
Assistant Professor
Division of Infectious Diseases
Department of Medicine
Vanderbilt University School of Medicine
Nashville, Tennessee
TERM: 10/21/03-06/30/07

LETT, Susan, M.D., M.P.H.
Medical Director
Division of Epidemiology and Immunization
Massachusetts Department of Public Health
Jamaica Plain, Massachusetts
TERM: 07/01/06-06/30/10

BAKER, Carol, M.D.
Professor of Pediatrics
Molecular Virology and Microbiology
Baylor College of Medicine
Houston, Texas
TERM: 07/01/06-06/30/10

LIEU, Tracy, M.D., M.P.H.
Professor and Director
Center for Child Health Care Studies
Department of Ambulatory Care and Prevention
Harvard Pilgrim Health Care and Harvard Medical
School
Boston, Massachusetts
TERM: 07/01/04-06/30/08

BECK, Robert L.
Consumer Representative
Palmyra, Virginia
TERM: 07/01/05-06/30/09

MORSE, Dale L., M.D.
Director, Office of Science and Public Health
New York State Department of Health
Albany, New York
TERM: 07/01/05-06/30/09

GILSDORF, Janet R., M.D.
Director, Pediatric Infectious Diseases
Department of Pediatrics and Communicable
Diseases
University of Michigan
Ann Arbor, Michigan
TERM: 07/01/06-06/30/07

MORITA, Julia, M.D.
Medical Director
Immunization Program
Chicago Department of Public Health
Chicago, Illinois
TERM: 07/01/04-06/30/08

HULL, Harry, M.D.
State Epidemiologist and Director
Minnesota Department of Health
St. Paul, MN
TERM: 07/01/05-06/30/09

NEUZIL, Kathleen, M.D., M.P.H.
Assistant Professor of Medicine
Division of Allergy and Infectious Diseases
University of Washington
Seattle, Washington
TERM: 07/01/06-06/30/10

STINCHFIELD, Patricia, NP
Director
Pediatric Infectious Disease & Immunology
Infection Control
Children's Hospitals and Clinics of Minnesota
St. Paul, Minnesota
TERM: 06/04/04-06/03/08

WOMEODU, Robin J., M.D.
Chief Medical Officer
Methodist Healthcare
University Hospital
Memphis, Tennessee
TERM: 10/13/03-06/30/07

SUMAYA, Ciro Valent, M.D., M.P.H.
Founding Dean
School of Rural Public Health and
Cox Endowed Chair in Medicine
Texas A&M University System Health
Science Center
College Station, Texas
TERM: 07/01/06-06/30/10

TREANOR, John J., M.D.
Professor of Medicine
Infectious Disease Unit
School of Medicine and Dentistry
University of Rochester
Rochester, New York
TERM: 07/01/05-06/30/07

EX OFFICIO MEMBERS

Indian Health Service

CHEEK, James E., M.D., M.P.H.
Director, Division of Epidemiology & Disease
Prevention
Office of Public Health Support
Indian Health Service
Albuquerque, New Mexico

Department of Defense

HACHEY, Wayne, DO, M.P.H.
LTC, USA, MC
Director, Deployment Medicine & Surveillance
Office of the Assistant Secretary of Defense
Force Health Protection and Readiness
Falls Church, VA

Health Resources and Services Administration

EVANS, Geoffrey S., M.D.
Director
Division of Vaccine Injury Compensation
Healthcare Systems Bureau
Health Resources and Services Administration
Rockville, Maryland

National Vaccine Program Office

GELLIN, Bruce, M.D., M.P.H.
Director
National Vaccine Program Office
Washington, D.C.

Centers for Medicare and Medicaid Services

MURPHY, Linda
Baltimore, Maryland

National Institutes of Health

CURLIN, George T., M.D.
Medical Director
DMID/NIH
Bethesda, Maryland

Food and Drug Administration

BAYLOR, Norman, Ph.D.
Director
Office of Vaccines Research Review
Rockville, Maryland

Department of Veterans Affairs

NICHOL, Kristin Lee, M.D.
Professor of Medicine
University of Minnesota
Chief of Medicine
VA Medical Center
Minneapolis, Minnesota

LIAISON REPRESENTATIVES

American Academy of Family Physicians

TEMTE, Jonathan M.D., Ph.D.
University of Wisconsin
Department of Family Medicine
Madison, Wisconsin

CAMPOS-OUTCALT, Doug, M.D.
Department of Family & Community Medicine
University of Arizona, College of Medicine
Phoenix, Arizona

American Academy of Pediatrics

BOCCHINI, Joseph A., Jr., M.D.
LSU Health Sciences Center in Shreveport
Children's Hospital of LSU
Health Sciences Center in Shreveport
Shreveport, Louisiana

TO BE DETERMINED

America's Health Insurance Plans

GELZER, Andrea, M.D.
Senior Vice President Clinical Public Affairs
CIGNA Corporation
Hartford, Connecticut

American College Health Association

TURNER, James C., M.D.
Executive Director, Elson Student Health Center
University of Virginia
Charlottesville, VA

American College of Obstetricians and Gynecologists

GALL, Stanley, M.D.
Department of OB/GYN
University of Louisville
School of Medicine
Louisville, Kentucky

American College of Physicians

TO BE DETERMINED

American Medical Association

TAN, LITJEN, Ph.D.
Director, Infectious Diseases, Immunology, &
Molecular Medicine
Chicago, Illinois

American Pharmacists Association

FOSTER, Stephan L., Pharm.D.
Associate Professor
CAPT (Ret) U.S.P.H.S.
University of Tennessee College of Pharmacy
Department of Pharmacy
Memphis, Tennessee

Association of Teachers of Preventive Medicine

McKINNEY, W. Paul, M.D.
Associate Dean for Public Health
University of Louisville School of Public Health &
Information Sciences
Louisville, Kentucky

Biotechnology Industry Organization

LEWIN, Clement, Ph.D., MBA
Vice President
US Government Affairs & Strategy
Cambridge,

Canadian National Advisory Committee on Immunization

NAUS, Monica, M.D.
Associate Director, Epidemiology Services
BC Center for Disease Control
Vancouver

Healthcare Infection Control Practices

Advisory Committee
GORDON, Steve, M.D.
Cleveland Clinic
Department of Infectious Diseases
Cleveland, Ohio

Infectious Diseases Society of America

KATZ, Samuel L., M.D.
W C Davison Professor and Chair Emeritus
Duke University Medical Center
Durham, North Carolina

London Department of Health

SALISBURY, David M., M.D.
Director of Immunization
Department of Health
London

National Association of County and City Health
Officials (NACCHO)

BENNETT, Nancy, M.D. (*until Oct 2006*)
Director, Center for Community Health
Professor of Medicine
University of Rochester School of Medicine &
Dentistry
Rochester, New York

DUCHIN, Jeffrey S., M.D. (*as of Oct 2006*)
Chief, Communicable Disease Control
Epidemiology and Immunization Section
Seattle, Washington

National Coalition for Adult
Immunization

NEUMANN, David A., Ph.D.
Executive Director
Partnership for Immunization
Alexandria, Virginia

National Foundation for Infectious Diseases

SCHAFFNER, William, M.D.
Professor and Chair
Department of Preventive Medicine
Vanderbilt University School of Medicine
Nashville, Tennessee

National Immunization Council and Child
Health Program, Mexico

RODRIGUEZ, Romeo S., M.D.
General Director
National Center for Health of Infancy and
Adolescence
Mexico

National Medical Association

WHITLEY-WILLIAMS, Patricia, M.D.
Professor of Pediatrics
Chief, Pediatric Infectious Diseases
UMDNJ-/Robert Wood Johnson Medical School
New Brunswick, New Jersey

National Vaccine Advisory Committee

FREED, Gary, M.D., M.P.H.
Division of General Pediatrics
University of Michigan
Ann Arbor, Michigan

Pharmaceutical Research and
Manufacturers of America

BRAGA, Damian A.
President, Sanofi Pasteur – US
Discovery Drive

PARADISO, Peter, Ph.D.
Vice President, New Business/Scientific Affairs
Wyeth Vaccines
Collegeville, Pennsylvania

Society for Adolescent Medicine

MIDDLEMAN, Amy B., M.D., M.P.H.
Associate Professor of Pediatrics
Baylor College of Medicine
Adolescent Medicine and Sports Medicine Section
Houston, Texas



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NIP sub-sites:

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- ▶ [Flu Vaccine](#)
- ▶ [Immunization Registries](#)
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National Immunization Hotline

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Recs > Provisional Recommendations

ACIP Provisional Recommendations

Last updated: December 20, 2006



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At a glance: This web page provides information for healthcare providers on the most recently voted upon recommendations of the ACIP that have yet to be officially approved by HHS and CDC.

Below are links to the most recent provisional recommendations of the Advisory Committee on Immunization Practices (ACIP). The ACIP voted for these recommendations; however, the recommendations are under review by the Director of CDC and the Department of Health and Human Services (HHS). They will become official when published in [CDC's Morbidity and Mortality Weekly Report \(MMWR\)](#).

Consult this page www.cdc.gov/nip/publications/acip-list.htm for a complete list of MMWRs on Recommendations of the ACIP related to vaccines and immunizations.

Links to ACIP Provisional Recommendations	Date ACIP Approved
Use of Shingles (Herpes Zoster) Vaccine (.pdf*) posted to website November 2006	October 2006
HPV (.pdf*) posted to website August 2006	June 2006
Varicella (.pdf*) update posted to website August 2006	June 2006 & June 2005
Use of Tdap among pregnant women (.pdf*) posted to website August 2006	June 2006

Red Book Online: Status of Licensure and Recommendations for New Vaccines*

Vaccine	Manufacturer	BLA submitted to FDA	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
MCV4 (Menactra®)	sanofi pasteur	Dec-2003	11-55 years of age	Licensed 14-Jan-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:116/2/496 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm
		Supplement to original BLA March 2005	2-10 years of age	To be reviewed	Pending FDA licensure
Varicella virus second dose (Varivax®)	Merck	Supplement to original BLA: second dose	Children 12 months to 12 years of age (3 month minimum interval)	Licensed 5-Apr-05	ACIP: cdc.gov/nip/vaccine/varicella/varicella_acip_recs_prov_june_2006.pdf AAP Recommendation: Pending
Tdap (BOOSTRIX®)	GlaxoSmithKline (GSK)	Jul-2004	10-18 years of age	Licensed 3-May-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:117/3/965 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm
Tdap (ADACEL™)	sanofi pasteur	Aug-2004	11-64 years of age	Licensed 10-Jun-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:117/3/965 CDC Adolescent: cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm CDC Adult: cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm?_cid=rr5517a1_e ACIP in Pregnancy: cdc.gov/nip/recs/provisional_recs/tdap-preg.pdf
MMRV (ProQuad®)	Merck	Aug-2004	Same as for MMR dose 1 or dose 2; 12 months to 12 years	Licensed 6-Sep-05	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5447a4.htm
Hepatitis A (VAQTA®)	Merck	Supplement to original BLA	Greater than or equal to 12 months	Licensed 15-Aug-05	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm AAP Recommendation: Pending
Hepatitis A (HAVRIX®)	GlaxoSmithKline (GSK)	Supplement to original BLA	Greater than or equal to 12 months	Licensed 18-Oct-05	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm AAP Recommendation: Pending
Rotavirus (ROTATEQ®)	Merck	Apr-2005	2, 4, and 6 months of age	Licensed 3-Feb-06	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5512a1.htm AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:119/1/171
Rotavirus (ROTARIX®)	GlaxoSmithKline (GSK)	2007	Pending submission	Pending BLA submission	Pending FDA licensure
Herpes zoster vaccine (ZOSTAVAX®)	Merck	Apr-2005	Greater than or equal to 60 years	Licensed 25-May-06	ACIP: cdc.gov/nip/recs/provisional_recs/zoster-11-20-06.pdf
Influenza (FLUARIX™)	GlaxoSmithKline (GSK)	May-2005	18 years of age and older	Licensed 31-Aug-05	CDC: cdc.gov/flu/about/qa/vaxprioritygroups.htm
Influenza (FluLaval™)	GlaxoSmithKline (GSK)	Mar-2006	18 years of age and older	Licensed 5-Oct-06	CDC: cdc.gov/flu/about/qa/vaxprioritygroups.htm
HPV (GARDASIL®)	Merck	Dec-2005	9-26 years of age (3 doses)	Licensed 8-Jun-06	ACIP: cdc.gov/nip/recs/provisional_recs/hpv.pdf AAP Recommendation: Pending
HPV (Cervarix™)	GlaxoSmithKline (GSK)	April 2007	Pending submission	Pending BLA submission	Pending FDA licensure
Hib/DTaP/IPV (PENTACEL™)	sanofi pasteur	Jul-2005	2, 4, 6, and 15 to 18 months	To be reviewed	Pending FDA licensure
CAIV-T (FluMist®)	MedImmune	Jul-2006	12 months to 59 months	To be reviewed	Pending FDA licensure

Table Updated: 2/6/07

Table available on Red Book Online: www.aapredbook.org/news/vaccstatus.shtml

BLA = biologics license application, VRBPAC = Vaccines and Related Biological Products Advisory Committee, FDA = Food and Drug Administration

AAP = American Academy of Pediatrics, ACIP = Advisory Committee on Immunization Practices, MCV4 = Meningococcal conjugate vaccine

MMRV = measles, mumps, rubella, varicella, Tdap = Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, adsorbed

HPV = human papillomavirus vaccine, Hib = Haemophilus influenzae b, DTaP = Diphtheria, Tetanus and Pertussis, IPV = Inactivated Poliovirus Vaccine, CAIV-T = Cold adapted influenza vaccine-trivalent

* information from vaccine manufacturers, from ACIP meetings and from AAP

** age licensure can change following FDA review; not final until package insert approved

*** ACIP recommendations do not become official until approved by the CDC Director and Department of HHS and publication in MMWR



