DEPARTMENT OF HEALTH AND HUMAN SERVIC S

PUBLIC HEALTH SERVICE

CENTERS FOR DISEASE CONTROL AND PREVENT)N

Minutes of Meeting

ADVISORY COMMITTEE ON IMMUNIZATION PRAC [CES
June 29 & 30, 1994

Atlanta, Georgia

ADVISORY COMMITTEE ON IMMUNIZATION PRACTI ES
Centers for Disease Control and Prevention
June 29-30, 1994
Auditorium A

JUNE 29

8:30 AM	Introduction	Dr. J. Davis Dr. D. Snider
9:00 AM	Implementation of "Vaccines for Children Program"	Dr. W. Orenstei Mr. D. Mason
9:30 AM	Scope of the "Vaccines for Children Program" Specific Wording for Hepatitis B	Dr. J. Davis CDC Staff
	BREAK	
	Second Dose MMR/MMR Catch-up Influenza and Pneumococcal Vaccines for High Risk Children	
11:30 AM	"Vaccines for Children Program:" Other Issues and Statement	Dr. S. Hadler
12:30 PM	**LUNCH**	
1:30 PM	Status of Simplification of Vaccine Schedule	Dr. J. Gindler Dr. S. Hadler
2:30 PM	IOM Report - Vaccine Safety DTP and Chronic Encephalopathy Other Vaccines	Dr. B. Chen Dr. G. Rabino ı Dr. K. Stratto ı Dr. J. Tuttle
4:00 PM	**BREAK**	
4:15 PM	Revised Hepatitis B Recommendation	Dr. F. Mahone Dr. H. Margol Dr. C. Stevens N.Y. Blood C ter
5:45 PM	**ADJOURN**	

JUNE 30

8:15 AM	Revision of Varicella Statement and Status of Application for Licensure	Dr. S. Holmes
8:30 AM	Revision of Polio Vaccine Recommendation	Dr. R. Sutter
9:30 AM	BCG Update	Dr. N. Halsey
9:45 AM	**BREAK**	
10:15 AM	National Vaccine Advisory Committee Report on Adult Immunization	Dr. W. Williams
10:30 AM	Wrap-up Issues on the Scope of the "Vaccines for Children Program"	Dr. J. Davis
11:30 PM	Update on the National Vaccine Program	Dr. A. Robbins NVP
11:45 AM	Injury Compensation Update	Mr. T. Balbier NVICP
12:00 PM	**LUNCH**	
1:00 PM	Influenza Antiviral Recommendations	Dr. N. Arden Dr. N. Cox
1:45 PM	Hepatitis A	Dr. C. Shapiro
2:30 PM	Status of Trials and Cost Benefit Analysis of Rotavirus Vaccines	Dr. J. Carmard Wyeth-Ayerst Dr. J. Eiden Merck Dr. R. Glass Dr. H. Paul Ma re American Cya mid Dr. P. Paradiso Lederle-Praxi Dr. J. Smith Dr. C. Jo Whit Merck
3:45 PM	Public Comment	
4:00 PM	**ADJOURN**	

ATTENDEES:

COMMITTEE MEMBERS PRESENT
Dr. Mary Lou Clements
Dr. Jeffrey Davis (Chair)
Dr. Barbara Ann DeBuono
Dr. Kathryn Edwards
Dr. Neal Halsey
Dr. Rudolph Jackson
Dr. Carlos Ramirez-Ronda
Dr. Steve Schoenbaum
Dr. F. Thompson (Conference Call)
Dr. Joel Ward

Ex Officio Members
Dr. Carolyn Hardegree (FDA)
Dr. G. Rabinovich (LaMontagne)

Liaison Representatives
Dr. William Butler (DOD)
Dr. David Fleming (HICPAC)
Dr. Pierce Gardner (ACP)
Dr. William Glezen (IDSA)
Dr. Caroline B. Hall (AAP)
Dr. Kristin Nichol (VA)
Dr. Georges Peter (AAP)
Dr. Anthony Robbins (NVP)
Dr. William Schaffner (AHA)
Dr. David Scheiffle (NACI)
Dr. Richard Zimmerman (AAFP)

Acting Executive Secretary
Dr. Dixie Snider

Office of the General Counsel
Mr. Kevin Malone

National Center for Infectious Diseases
Dr. Nancy Arden
Dr. Joseph Bresee
Mr. Jay Butler
Dr. Martin S. Favero
Jay Butler
Jon Gentsel
B. Jiang
Dr. Frank Mahoney
Eric Mast
Dr. Gary Sanden
Dr. Craig Shapiro
Thomas Shinnick

National Center for Preventi Services
Rosamond Dewart

National Immunization Prog n
Dr. William Atkinson
Dr. Francisco Averhoff
Dr. Bob Chen
Dr. Vance Dietz
Christina Drummond
Dr. Gary Euler
Judy Gantt
Edith Gary
Penina Haber
Dr. Steve Hadler
Iain Hardy
Janet Hardy
Dr. Sandra Holmes
Dr. Sonja Hutchins
Dr. Gail King
Dr. Arthur Manoharan
Dr. W. Orenstein
Dr. Peter Strebel
Dr. Ray Strikas
Dr. Roland Sutter
Raffi Tachdjian
Dr. Walter Williams
Dr. J. Watson
Dr. Melinda Wharton

Office of Public Affairs
Kay Golan

Agency for Toxic Substance nd Disease Registry
Rita Ford
Lynda Nation

Department of Defense
Dr. Michael Peterson

Food and Drug Administrat n
N.W. Baylor
Sean Dowdy
Stephen Feinstone
Karen Goldenthal
Karen Midthun
Dr. Margaret Mitrane
Dr. Linda Teague
Robert Yetts

ATTENDEES CONTINUED:

HHS - Office of the Inspector General
Betty Apt
Ballard O. Hillman
Leah Nolan

National Institutes of Health
Dr. Albert Z. Kapikian

Navy Environmental Health nter
Dr. Robert Brawley

Army Surgeon General's Of e
Dr. Vincent P. Fonseca

Others Present
Sheryl Beeks, The Prudential Health Care System
Florence Berut, Connaught Laboratories Inc.
Dr. Dee Breeden, S.C. Department of Health and Environmental Control
Joseph Camardo, Wyeth
Jill Chamberlin, Vaccine Bulletin
Janet Crawford, Merck Vaccine Division
Lara Creasy, American Health Consultants
Dr. Ruth Ann Dunn, Michigan Department of Public Health
Dr. Joseph Eiden, Merck Research Laboratories
Dr. Geoffrey Evans, Division of Vaccine Injury Compensation
Steve Frandel, Medical Tribune
Carol Frankel, Evans/Medeva
Christine Grant, Connaught Laboratories Inc.
Valerie Greenwood, Merck & Company
Dr. Jill Hackell, Lederle-Praxis Biologicals
Clifton N. Irby, Christian Science Committee
Bob Jacobson, Mayo Clinic
Cheryl Pokalo Jones, Infectious Diseases in Children
Kathy Jordon, NAPNAP
Dr. Samuel Katz, Duke University Medical Center
Dr. David Krause, Smith- Kline, Beecham
Barbara Kuter, Merck
Brian Lortie, Smith, Kline, Beecham
Dr. Tyler Martin, Biocine
Dr. Carlton Meschievitz, Connaught Laboratories
Diane Mitriune, Smith-Kline, Beecham
Wayne Morges, Merck & Co., Inc.
Dr. David Nalin, MRL
Jeff Natkin, Forest Laboratories
Marjorie Nicholls, Forest Labs
Peter Paradiso, Lederle-Praxis Biologicals
Lorraine Radick, Lederle-Praxis Biologicals
Anne Rochell, Atlanta Journal-Constitution
Dennis Schaffer, SBCRCTECH, Inc.
Judith Shindman, Connaught Laboratories, Ltd.
Dan Soland, Smith, Kline, Beecham
Dale R. Spriggs, VRI, Inc.

ATTENDEES CONTINUED:

Kathleen Stratton, Institute of Medicine
Barbara Sweeney, NAPNAP
Ron Thiboutot, Wyeth-Ayerst Laboratories
Miriam E. Tucker, Pediatric News
Thomas Vernon, Merck Vaccine Division
Richard Ward, Gamble Institute
George Welu, Connaught Laboratories, Inc.
David West, Merck Laboratories
Dr. Jo White, Merck Research Laboratories
Tim Wissman, Merck & Co.
Dr. Barbara A. Zajac, Wyeth-Ayerst
Dr. Edward T. Zito, Wyeth-Ayerst Research

Summary of Agreed-Upon Actions

Revision of the ACIP pneumococcal statement will be a topic for the next A IP meeting.

Dixie Snider agreed to having the FDA and vaccine manufacturers' input o contraindications before the next meeting.

All members are to return comments on handout #2 (draft for physicians i he VFC program, entitled "Establishment of the List and Schedules of Pediatric Va nes to be Purchased and Administered Under the "Vaccines for Children Program,") urned to Ms. Gloria Kovach by July 17.

Dr. Hal Margolis agreed to distribute data from immunization program m: igers survey about hepatitis to ACIP members.

ACIP members are to return comments on the proposed ACIP Poliomyeliti revention statement to Ms. Kovach by the end of July.

FDA agreed to have information by the fall ACIP meeting regarding the c bination polio vaccine and the dual-chamber one.

The next meeting will include an update on Canada's experience with the io conjugate vaccine.

Dr. Gina Rabinovich will make copies of the *Jordan Report-- 1993: Acceler d Development of Vaccines* available to each member of the ACIP.

ACIP members are to return comments about the proposed BCG ACIP st ment to Dr. Halsey by July 15.

ACIP members are to return comments about the revised ACIP statement varicella to Ms. Kovach by July 30.

Dr. Margolis is to provide advanced copies of the beginnings of an ACIP s ement on hepatitis A vaccine--as well as a list of issues--to all members of the newly med working group on this subject before its first meeting.

ACIP members are to send information to Dr. Arden about the antivirals CIP statement by July 15.

Dr. Jeff Davis, Chairperson of the Advisory Committee on Immunization P ctices (ACIP), called the summer meeting to order on June 29, 1994, at 8:35 a.m t the Centers for Disease Control and Prevention (CDC).

Dr. Dixie Snider, Acting Associate Director for Science for CDC and Actin Executive Secretary for ACIP, announced that Dr. Schoenbaum had been appointed a new ACIP member, and Dr. William Butler was replacing Dr. Michael Peterso s the liaison member for the Department of Defense. In addition, two members ere rotating off the committee: Dr. Ramirez-Ronda and Dr. Clements. Dr. Snider als nnounced that the new ACIP charter states that ex officio members would no longer voting members.

Dr. Davis congratulated Dr. Claire Broome on being named Deputy Direct of CDC.

Potential Conflicts of Interest

Approximately 100 people in attendance introduced themselves, followed b introductions and declarations of potential conflicts of interest by the app ted members.

Dr. Joel Ward has no financial interest in any pharmaceutical company. e Research Institute at UCLA, which he directs, receives some funding from Merck & ompany and SmithKline Beecham (SKB). He also attended meetings funded by M k, SKB and Lederle in the last 12 months.

Dr. Kathy Edwards works in an NIH-funded evaluation unit which has re ved some funding from Evans-Medeva. She is also an unpaid consultant for Institut Merieux; has done some consulting for SKB; and is on the speaker's bureau for Co ught and Lederle.

Dr. Steve Schoenbaum has no consulting relationship with any pharmaceu al company. His wife has stock in Abbott Laboratories, Amgen Inc., Bristol Myers Squ b, Glaxo, and Merck.

Dr. Mary Lou Clements is testing vaccines in collaboration with Wyeth ar Merck; has consulted with Virus Research Institute; and has attended a meeting for M). She is also involved in the testing of AIDS vaccines for Pasteur Merieux, Connau t, Virogenetics, Genentech, Chiron, Biocene, and a number of other compar .

Dr. Neal Halsey has no financial interest in any of the vaccine manufactu s; he has received grant support in the last 12 months from Pasteur-Merieux, Conn ght Labs, and SKB. He has received travel support from SKB and has been promi such support from the Consortium of European Manufacturers.

Dr. Ramirez-Ronda has no financial interest in the drug industry, but his ; up has received funding in the last 12 months from Bristol-Myers Squibb and Bur ıghs Wellcome, none vaccine related.

Drs. Davis and DeBuono had no potential conflicts of interest.

Voting Explained

Dr. Davis explained that only ACIP appointed members could vote and tha 'otes would be announced, by name, with absences and abstentions noted. Quorum is 'or a committee of 10. Abstentions count toward the quorum.

Two members expressed concern that the ACIP's ability to control public l lth policy is severely compromised by requiring abstentions for the potential conflicts interest, as defined. Dr. Neal Halsey asked the record to state that he had written , Claire Broome, formally proposing CDC undertake a review of this process with intent of liberalization so members could vote on these issues. Dr. Davis said that tl letter would be distributed to all members of the Committee.

Dr. Snider said he was sympathetic to this concern and he would agree tha CDC should commit to undertaking such a review. He also said that Ladene Newton, f ner Ethics Officer, for CDC, had said that multi-company support is not a conflict of terest. He also asked that Dr. Halsey's letter be distributed to all members of the Co ıittee.

Implementation of the Vaccines for Children (VFC) Program

Dr. Walt Orenstein, Director of the National Immunization Program (NIP eviewed the VFC program and reviewed ordering and distribution procedures. Mı Kevin Malone from CDC's legal counsel, briefly reviewed aspects of the VFC tha elated to ACIP, basically: that states can establish other classes of children who the ant to provide vaccines for; that the ACIP will establish vaccines for the VFC; th VFC vaccines may be provided to eligible children, as required by state immuni ion laws; and that once Health Care Reform is implemented, Congress initially inte d that this program would cease.

Scope of the VFC Program

Dr. Davis summarized the June 8th working group meeting on this subjec It was attended by the appointed ACIP members (Drs. Ward and Jackson and D is), liaison members (Drs. Gleason, Schaffner and Fleming), and 17 CDC staff memb ;. Dr. DeBuono could not attend, but sent documents expressing her preferences The group considered additional vaccines and risk groups for inclusion in the VFC p ram, including hepatitis B for specific high-risk groups and for adolescents, MM -2 for additional cohorts, and influenza and pneumococcal vaccination for high- ; children.

Issue for Vote: Vaccination with a second dose of MMR vaccine for more tha one cohort of children

Dr. Gail King, NIP, summarized for the working group different recomme ed options and their costs and their final recommendations, which are described in at hment A and are included in the following item for vote:

> The ACIP recommends that the VFC program for October 1994 sh d include one cohort of children (≤ 18 years of age) to receive a second dose MMR in each state, and should include vaccination of any eligible children (8 years of age) who are required by state laws or state university or college Re nts' policies to receive a second dose of MMR or measles vaccine prior to attend ce in schools or colleges.

Potential conflict of interest for this vote was support from or financial int st in MSD. This vote passed 6-0. (for: Drs. Davis, Ramirez-Ronda, DeBuono, Edwar , Thompson [who joined the group by conference call] and Halsey; 0, opposed; abstain Drs. Schoenbaum, Ward and Clements; and 1 absentee (Dr. Jackson).

Issue for Vote: Expanding the MMR vaccine to two cohorts

The next item for vote was:

> The ACIP recommends that in the FY 1996 year (beginning Octobe 995), the VFC program should be expanded to provide a second dose of MM vaccine to two cohorts of children in each state, in addition to those whose va nation is required by state law or Regents' policy.

The issue went back to a Committee (Drs. Fleming, Davis and King) for r hrasing.

Issue for Vote: Influenza vaccination of high-risk children

Dr. Ray Strikas, NIP, summarized the discussion of the June 8th working oup meeting on this subject, which examined disease burden indicators. The A IP working group recommended that the VFC program for October 1994 should not i lude influenza vaccination of children at high risk of complications of influenza isease. The ACIP decided by consensus not to vote on this, since Mr. Malone suggeste hat the ACIP need not formally vote on negative issues.

The working group also made the following proposal for vote:

> The ACIP recommends that influenza vaccination for persons in hi risk groups should be added to the VFC program in FY 1996.

Potential conflict of interest for this vote was support from or financial inter in Connaught, Pasteur-Merieux, Park Davis, Wyeth-Ayerst, or Evans-Abbott L oratories. The measure passed 5-1, with the stipulation that the precise groups to be in ded in the program would be determined in a separate vote next year (For: Drs. R irez-Ronda, Clements, Schoenbaum, Ward, and Davis; Opposed: Dr. DeBuono; staining: Drs. Halsey, Edwards and Thompson; 1 absentee.) [Note: Dr. Thompson dis sed his potential conflict of interest with Connaught, after joining the meeting by co erence call, before this vote.]

Issue for vote: Pneumococcal vaccination of high-risk children

Dr. Strikas summarized the groups for whom pneumococcal vaccination is recommended (see attachment A) and various implementation issues.

For the record, Dr. Ward noted that too many unsupported conditions are l d in the ACIP document on this subject and it really needed to be rewritten, though t now. He asked that this subject be added to the agenda for a future meeting. Dr. avis agreed to do this.

The issue for vote, proposed by the working group, is as follows:

> **The ACIP recommends that pneumococcal vaccination of children (≤ 3 years of age) at high risk of this disease, as defined above [by the ACIP guide es for pneumococcal vaccination for children], be included in the Vaccines f Children program. The schedule and dosage for vaccination should be those d ned above [by the ACIP].**

Potential conflicts of interest for this vote were support from or financial in est in Merck or Lederle. The vote passed 4-0, with 5 abstentions (For: Dr. Ram z-Ronda, DeBuono, Halsey and Davis; opposed: none; Abstaining: Drs. Schoenbaum, ements, Edwards, Ward and Thompson; absent: Dr. Jackson).

<u>VFC Program: Contraindications and Precautions</u>

Dr. Steve Hadler introduced the next issue for discussion and vote: contrain ations and precautions. Dr. Hardegree made a statement for the record from FD bout the inconsistency of the package inserts and ACIP recommendations. It was ag d that this is a concern and should be done a month before the next meeting, but t it not hamper voting now.

Issue for Vote: Contraindications and Precautions for vaccines to prevent dipht ia-tetanus-pertussis (DTP)

Dr. Hadler reviewed the contraindications and precautions for DTP vaccines nd proposed the following for vote:

> **The ACIP recommends that the contraindications and precautions for se of vaccines containing DTP and DTaP specified above, with the specific clarifications listed [see attachment B], be included in the Vaccines fo Child Program.**

Potential conflicts of interest for this vote were support from or financial int st in Lederle, Connaught, or the Michigan and Massachusetts Departments of He h. This measure passed 6-0, with 2 abstentions and 2 absentees [For: Drs. DeBuono Ramirez-Ronda, Clements, Schoenbaum, Ward, and Davis; against: none; abstaining Drs. Halsey and Edwards; absentees: Thompson and Jackson].

Issue for Vote: Contraindications and Precautions for vaccines to prevent Dip eria and Tetanus Toxoids

The proposal for vote was:

> **The ACIP recommends that the contraindications and precautions fo se of diphtheria and tetanus toxoid containing vaccines as specified above e attachment B, p. 7, with change to item #2, indicating that GBS case re rare] be included in the Vaccines for Children program.**

Potential conflicts of interest for this vote were Lederle, Connaught, Wyeth- erst and the Michigan Department of Health. This vote passed 6-0 [For: Drs. Rami -Ronda, DeBuono, Clements, Schoenbaum, Ward and Davis; against: none; abstaini : Drs. Halsey and Edwards; and absent, 2 [Drs. Jackson and Thompson].

Issue for vote: Contraindications and Precautions for vaccines to prevent mea s-mumps and rubella (MMR)

Dr. Hadler reviewed these [see attachment B, pp. 8-10]. To item #4 (attac ient B, p. 8), "known altered immunocompetence, the phrase "(except HIV infection; text") was added. And to precaution #2 (attachment B), the phrase "see table 1" added). Dr. Davis then read the following proposal for vote:

> **The ACIP recommends that the contraindications and precautions fo ise of MMR and measles, mumps, and rubella containing vaccines specifie bove, with the specific clarifications listed above, be included in the Vaccines fo Children program.**

This subject, explored on p. 16 of attachment B, involved the following vot

> **The ACIP recommends that the contraindication for use of *Haemophi* *influenza* type b conjugate vaccines specified above be included in the** **ıccines** **for Children program.**

Potential conflicts of interest for this vote were support from or financial int st in Connaught, Lederle, Merck, or SKB. This vote carried, 3-0, with 6 abstenti s and l absentee [for: Drs. Ramirez-Ronda, DeBuono, and Davis; opposed: none; al ıining: Drs. Halsey, Clements, Schoenbaum, Edwards, Ward, and Thompson; abse Dr. Jackson].

Issue for vote: Contraindications and precautions to vaccines to prevent pneun occal infection

Potential conflicts of interest for this vote were support from or financial int st in [summarized on p. 17 of attachment B] Merck or Lederle. The issue for vc was:

> **The ACIP recommends that the precaution for use of pneumococcal polysaccharide vaccine specified above be included in the Vaccines fo hildren program.**

The vote carried 5-0 [For: Dr. Ramirez-Ronda, DeBuono, Thompson, Hals and Davis; against: none; abstaining: Drs. Clements, Schoenbaum, Edwards, ar Ward; absent: Dr. Jackson].

Issue for vote: Contraindications and precautions to administration of any chi ıood vaccine

Contraindications and precautions are an anaphylactic reaction or moderat r severe illness with or without fever. Following discussion, the following amendmer explaining the second point, was added to page 18 of attachment B: "Persons with n lerate or severe febrile illness should be vaccinated as soon as they have recovered fr the acute phase of the illness." The wording for vote was as follows:

> **The ACIP recommends that the contraindications for use of vaccines specified above be included in the Vaccines for Children program.**

Since this was a general issue, no one was excused from voting. The vote ca ed unanimously, with one absentee [Dr. Jackson].

Additional Vaccines for Children Issues for Vote

Dr. Hadler brought up three additional matters for vote.

Issue for Vote: Acceptability of Recommendations of the Committee on Infect s Diseases, American Academy of Pediatrics

Dr. Hadler reviewed the major and minor differences between ACIP and A recommendations. The vote was the following:

> **The ACIP recommends, for those pediatric vaccines recommended b ıe ACIP for purchase in the Vaccines for Children program, that all recomm lations for uses of childhood vaccines described by the Committee on Infectious seases of the American Academy of Pediatrics in the publication 1994 Red Bo Report of the Committee on Infectious Diseases be considered acceptable for th Vaccines for Children program, unless specifically prohibited in the previousl oted recommendations, or for the following exceptions:**
>
> > **The purchase of hepatitis B vaccine for all children and adole nts is not currently recommended to be included in the Vaccines for Ch ren program, except for the recommendation for universal vaccin on of all infants born after November 22, 1991, and vaccination of all ldren who belong to specific risk groups defined in previous votes.**
> >
> > **The use of the *Haemophilus influenzae* type b conjugate vacci PRP-D as a two-dose series for children at 12 and 15 months of age is n recommended for children participating in the VFC program.**
> >
> > **Monovalent pertussis vaccine will not be made available for c oreak control in the Vaccines for Children program.**

There were no conflicts of interest, and the vote carried unanimously with o absentees [Drs. Ward and Jackson].

Issue for Vote: Clarification of Consistency of Use of Hib Vaccines for the I Primary Series

This vote repealed resolution 2/94-7--because the wording "if feasible" was clear to legal experts--and rephrased for vote as follows:

> **The primary vaccine series should be completed with the same Hib cine, if known and available. However, if different vaccines are administer , a total of 3 doses of Hib vaccine is considered adequate for the primary series nong**

infants, and any combination of Hib conjugate vaccines licensed for e among infants may be used to complete the primary series.

The suggestion to have a separate paragraph defining "if feasible" was reje d. Potential conflicts of interest for this vote were support from or financial i rest in Connaught, Merck, Lederle, or SKB. The vote carried 3-0, with 6 absten ns [For: Drs. Ramirez-Ronda, DeBuono, and Davis; against: none; abstaining: Drs [alsey, Clements, Schoenbaum, Edwards, Ward, and Thompson; absent: Dr. Jac n].

Issue for Vote: Dosages of Vaccines Recommended for the Vaccines for Chil n Program

The proposal for vote on this issue was worded as follows:

The ACIP recommends that pediatric vaccines recommended for use the Vaccines for Children program should be administered in dosages a recommended by the vaccine manufacturers in the current FDA-app ved package inserts.

This measure passed unanimously, with 1 absentee (Dr. Jackson).

Dr. Hadler asked that comments on "Establishment of the List and Sched s of Pediatric Vaccines to be Purchased and Administered Under the "Vaccines r Children Program," which is to eventually be distributed to physicians in the VFC p gram, be returned by July 17th to Ms. Kovach or Dr. Hadler.

Issue for Vote: Outbreaks

It was then pointed out that the VFC program schedule applies to routine circumstances. However, during emergencies such as a outbreaks, other c ldren who qualify for the VFC program will need VFC vaccines. Therefore, the follo ng proposal was submitted for voting:

The ACIP recommends that state and local health authorities be giv flexibility to provide vaccine purchased by the VFC program for additional V -eligible children during outbreaks provided that those outbreak control mea res are consistent with existing ACIP recommendations.

There were no potential conflicts of interest for this vote, which passed un mously with one absentee (Dr. Jackson).

IOM Report: Vaccine Safety

Dr. Bob Chen, NIP, introduced this topic and the other speakers. Dr. Jes a Tuttle summarized the 10-year follow-up on the National Childhood Encephalopa y Study and

Potential conflicts of interest was support or financial interest from Merck. is measure passed, 5-0, with 4 abstentions [for: Drs. Ramirez-Ronda, DeBuon Halsey, Edwards, and Davis; against: none; abstaining: Drs. Clements, Schoenbaum, Ward, and Thompson; absent: Dr. Jackson].

Issue for vote: Contraindications and precautions for vaccines to prevent polio elitis

Dr. Hadler reviewed these [see attachment B, pp. 12-14]. The only amendn t to these pages was to name the antibiotics that can cause anaphylactic reactions nder the section "Inactivated polio vaccine." The issue for vote was:

> **The ACIP recommends that the contraindications and precautions for e of OPV and IPV specified above, with the specific clarifications listed ab e, be included in the Vaccines for Children program.**

Potential conflicts of interest for this vote were support from or financial int st in Connaught or Lederle. This vote carried, 6-0, with 3 abstentions [for: Drs. amirez-Ronda, DeBuono, Clements, Schoenbaum, Ward, and Davis; against: none; staining: Drs. Halsey, Edwards and Thompson; and absent: Dr. Jackson]. In this dis sion Dr. Snider committed to having FDA and manufacturers' input on contraindicat ns before the next meeting.

Issue for vote: Contraindications and precautions to vaccines to prevent hepati B virus infection

This subject, stated on p. 15 of attachment B, involved the following vote:

> **The ACIP recommends that the contraindication for use of hepatitis B vaccine specified above be included in the Vaccines for Children program.**

Potential conflicts of interest for this vote were support from or financial int est in Merck or SKB. This vote carried, 5-0, with 4 abstentions [for: Drs. Ramir Ronda, DeBuono, Davis, Thompson, and Ward; against: none; abstaining: Drs. Hal , Clements, Schoenbaum, and Edwards; and Dr. Jackson absent]. **Note: Lat , Dr. Ward changed his vote to an abstain, because he had a Merck potential con t of interest. Thus, the final tally was 4-0.**

Issue for vote: Contraindications and precautions to vaccines to prevent Haem hilus influenzae type b infection

its reported association between pertussis and acute and chronic encephalopa y. That study concluded that cases were more likely than controls to have died or ha ignificant dysfunction on 10-year follow-up (Cases were also more likely than controls have received DTP within 7 days of onset of encephalopathy.) Following her pres cation, Dr. Halsey asked that the record reflect his objection that these data were n valid because the two matched controls for each case were not followed.

Dr. Kathleen Stratton from the Institute of Medicine (IOM) noted that the I M had reviewed this issue and concluded that the Miller methodology was valid. D Stratton then reported on the IOM 's review and the new Miller study. The committ reached three conclusions: 1) that the evidence was insufficient to indicate whether not DTP increases the overall risk in children of chronic nervous system dysfunction; that the balance of the evidence is consistent with a causal relation between DTP and e forms of chronic nervous system dysfunction described in the NCES in those childr who experienced a serious, acute neurologic illness within 7 days after receiving I P vaccine; and 3) that the evidence was insufficient to indicate the presence or sence of a causal relation between DTP and chronic nervous system dysfunction unde ny other circumstances.

Dr. Gina Rabinovich reviewed the National Vaccine Advisory Committee's a hoc subcommittee on childhood vaccines' one-day meeting on the same subject. is expert review resulted in the following conclusions: the experts concurred with the M reports and conclusions in 18 of 22 areas reviewed; the experts concurred with CDC Vaccine Injury Compensation Board, and FDA staff proposals in 20 of 22 areas revi ed. There were seven areas where the ad hoc committee did not concur with th OM reports or gave additional comments.

Revised Hepatitis B Recommendation

The above discussion was halted for Cladd E. Stevens, from the N.Y. Blood enter, to review a series of studies in high-risk, mostly Asian-American infants in the nited States. Conclusions from these data are that: 1) low-dose (2.5 microgram) ombinant hepatitis B vaccine with hepatitis B immune globulin is as effective as a 5-m ogram dose; 2) the extended vaccination schedule (0-, 2-, 4-, and 15-month schedu seems to give a higher post-booster antibody level than the 0-,2-,and 6-month schedu 3) most infants retain protective levels of antibody for at least 5 to 10 years; 4) lon erm persistence of antibody was related to the level of initial antibody response; there was overall a low incidence of hepatitis B infection long-term.

Vaccine Safety--IOM Report (continued)

Dr. Chen requested that the ACIP delegate a representative to the already rmed IOM working group, discussion of DTP and chronic encephalopathy and of GBS a

contraindication to receiving tetanus-toxoid-containing vaccines. Dr. Peter ; asked to join this working group.

With Dr. Tuttle leading discussion, the ACIP decided to leave as written the scussion of OPV.

> **The available data do not indicate any measurable increased risk of G following OPV. Initial evidence (at the time of IOM review) based or ecological studies done in Finland favored acceptance that OPV could These studies observed an apparent increased incidence of GBS tempo associated with a mass immunization with OPV in both children and had previously received IPV[14]. Since the IOM review, reanalysis of th data and an observational study done in the U.S. have provided evide a causal relationship between oral polio vaccine administration to infa GBS[15].**

The suggested wording on whether thrombocytopenia is an adverse event fol MMR was also referred to the working group to determine whether to add t of thrombocytopenia after natural measles infection is higher than the risk a

The last point for discussion was subacute sclerosing panencephalitis (SSPE) vaccine. The ACIP agreed with the following wording :

> Measles vaccine significantly reduces the possibility of developing SSI evidenced by the marked decline in the number of SSPE cases noted widespread measles immunization. Subacute sclerosing panencephali rarely reported in children with no history of natural measles infecti history of receiving measles vaccine. There is evidence to support th some of these children had unrecognized measles infection prior to in and that the SSPE was directly related to measles infection. The adr of live measle vaccine does not increase the risk of SSPE in individu measles infection or had previously received live measles vaccine.

Dr. Chen then asked the ACIP how they wished to disseminate the revised these ACIP statements. He suggested creating an MMWR supplement cont executive summaries for all the IOM reports with tables and a summary of precautions and contraindications and then to have inserts in the current A statements as they are updated. The group agreed, by consensus, to follow with the caveat that an introduction on the safety of the vaccines be added.

The meeting adjourned for the day at 6:20 p.m., after Dr. Davis changed t to start at 8:00 a.m. the following morning. The meeting began at 8:10.

Revised Hepatitis B Recommendation—continued

Draft ACIP Statement

Dr. Margolis discussed the draft ACIP statement on hepatitis B virus, empha ing that he thought it could be made more user friendly by separating the backgroun information, having sidebars of key summary points and an index of key wo and topics to access information; separating out the recommendations, with sumn y tables; have a preamble to what's new; and anticipate incorporating this draft with hepatitis A virus statement in the future. An ACIP member said he thought the statements should be more user friendly and that CDC should explore hiring consultant to do this.

Dr. Margolis then went over technical updates, noting that long-term protect persists even with declining antibody levels. Dr. Frank Mahoney reviewed data on s ral studies that identified risk factors for nonresponse to vaccination among adu He also reported on a prospective study using the two currently licensed vaccines (Re nbivax and Engerix) in adults. The study population was generally older health-car orkers (HCWs) with a mean age of 43. The study found that the difference in resp e rates between the currently licensed vaccines was primarily in persons >40 years age.

Dr. Francisco Averholf presented data from a study on risk factors for nonr onse to hepatitis B vaccines. Smoking, obesity, male gender, chronic disease, and in easing age were all risk factors. Response rates to re-vaccination were greater than % for both vaccines.

Dr. Mahoney summarized by saying that, though there is a difference in the o vaccines among persons ≥40, this difference is not felt to be of public healt importance. The ACIP was asked if the FDA should be asked to examine if e dose level is enough for Recombivax. It was decided that the refined analysis sho l be distributed to members before this could be decided.

Adolescent hepatitis B

Dr. Margolis reviewed the epidemiology of this infection. Only 4%-8% of in ctions occur in children; the rest occur in adults and adolescents. He also reviewe osts of the vaccine and delivery and cost-effectiveness data for adolescents compare o infants. Finally, he said that when immunization program managers are surveyed, 7 would like to see 11-to 15-year-olds immunization against hepatitis B. Dr. Margoli greed to distribute these data to all the ACIP members.

Two different working groups were formed to explore the issues about adole nt and adult hepatitis B immunization. Volunteers for the adult working group we Drs. Fleming, Schoenbaum, and Pierce Gardner. Volunteers for the adolescent g ıp were Drs. Zimmerman, Halsey, Ward, Peter, Dr. Rudy Jackson, and Davis.

Revision of Polio Vaccine Recommendations

Dr. Roland Sutter, NIP, reviewed the revised ACIP statement on polio prev ion, pointing out the major and minor issues for consideration. The revised vers ı has an expanded introduction and added paragraphs on acute polio, post-polio sync me, epidemiology, and laboratory methods. Sections on precautions and contrai ications (GBS has been added), epidemic control, the vaccine injury compensation p ;ram, the eradication of polio, and immunocompromised persons have been added. T group rejected the addition of a statement that "OPV should not be administered t ı child with diarrhea." Also, the word "kissing" was deleted as a form of contact ı be avoided with immunodeficient household contacts of OPV recipients.

Dr. Sutter then pointed out the major issues he wished members to consider hen reviewing the draft: 1) OPV is explicitly stated to be the vaccine of choice f the primary immunization of children; 2) no paragraph has been added dealing ith sequential schedules nor with the anticipated licensure of combination vacci ; 3) no paragraph exists on provocation polio; 4) the time when the first dose of OI should start has been lowered to 6-8 weeks; 5) The minimum interval between IPV ıses has been lowered to 4 weeks for adults requiring immediate protection against ı poliovirus; 6) immunization is recommended for HCWs in close contact wit ıatients who may be excreting poliovirus; 7) regarding pregnancy, it has been adde ıat OPV and IPV can be administered.

Members agreed to send comments to Ms. Kovach before the end of July. ıe FDA was requested to have information by the fall meeting on the status of the ı ıbination polio vaccine with the dual chamber. Canada was requested to present dat ın its conjugate vaccine, now being used in most provinces.

Status of Simplification of the Vaccine Schedule

Dr. Hadler reviewed the goal of having a single schedule with a comprehen e format. He said that the working group appointed at the February ACIP meeting (s. Halsey, Edwards, and Thompson from the ACIP; Drs. Hall, Peter, and Halsey fro AAP; Dr. Rick Zimmerman from AAFP; Dr. Hardegree representing FDA; and Dr. binovich, representing NIH) developed routine schedules that gave a specified time fo administration of each dose for each vaccine but also showed an acceptable ınge of ages for each dose. Current recommendations were not changed. Dr. Had reviewed the resulting draft schedules for parents and physicians, respectively.

The manufacturers then made comments. Dr. Carlton Meschievitz, from Co aught-
Merieux, said that 1) he viewed the changes as more than subtle, since the V
program makes the schedules requirements, not just recommendations; 2) in e
documents he has received, he didn't see anything regarding vaccines for hig risk
(HIV) individuals; 3) his manufacturer thinks it would be more appropriate target
vaccines closer to 15 months, not 12 months, if all are to be given simultane ly. 4)
Connaught would like to see the current ACIP recommendations regarding a lular
pertussis be maintained; Connaught is planning to submit an application this ear for a
combination DT acellular pertussis and Hib vaccine as an injection in the sec d year of
life; 5) Connaught would like to emphasize that it wants to be partners with e ACIP
and NIP--to be included more--in this process.

Dr. Tom Vernon from Merck concurred with Dr. Meschievitz' comments, p icularly
his comments regarding safety and the apparent demotion of the use of DTa Dr.
Vernon then asked Dr. David West to speak on the hepatitis B scheduling. , West
said that Merck agrees with the ACIP that it is important to have vaccine tr data that
validate different and useful (and more flexible) immunization schedules. M ck has
submitted additional data from Recombivax (Hepatitis B) trials to the FDA recently
as January 1994 in response to a request published in the Federal Register. erck will
continue to provide such data as trials are completed. He emphasized that i emains
important for package insert recommendations to be based upon the results trials,
given the requirements of the FDA and the existing medical-legal environme

Jill Hackel from Lederle, reiterated the other speakers' comments about the ed and
desire for the manufacturers to be partners with policy-forming bodies. She so pointed
out that manufacturers play a part in the education process in disseminating osters and
schedules to parents and physicians; if those materials conflict with ACIP
recommendations, that's a problem.

Following this presentation, ACIP members said they frankly needed more ormation
sharing about manufacturers' plans for vaccine studies. It was suggested th the
vaccine manufacturers be given 45 minutes at a future meeting to talk abou
combination products. Dr. Tony Robbins said that the NVP has set up a su ommittee
on future vaccines that includes manufacturers and FDA advisory committe nembers.
He also suggested that the FDA may need to start a regular process of upda ng vaccine
labels. Dr. Davis asked for regular progress reports to the committee on th

Mr. Malone noted, regarding the issue of liability concerns associated with -label use,
that off-label use by providers is not prohibited and secondly, the flexibility the
schedules approved by ACIP will never compel a particular provider to pro le vaccine
off-label, it will merely give them the opportunity, if they choose to. In oth words,
it's not illegal to provide a vaccine off-label, as long as the vaccine is licens

Dr. Rabinovich said she would make copies of the *Jordan Report-- 1993: Acc rated Development of Vaccines* available to each member of the ACIP.

Update on the National Vaccine Program

Dr. Tony Robbins distributed the Prepublication draft of the U.S. National ccine Plan for 1994, distributed in June, which provides an update on the use of 2 icensed vaccines and the development of over 50 new and improved vaccine candida . He reviewed the history of the NVP and briefly reviewed its vision of accelerate development of new vaccines.

Update on the Injury Compensation Update

Dr. Thomas Balbier spoke via television/satellite hookup on the National Va ne Injury Compensation Program. He said that in June a former petitioners' attorney ho represented about 250 petitioners, was sentenced to criminal charges regardi theft of $1.4 million. Regarding claims, 55 claims have been filed in fiscal year 199 for a cumulative total of 4,629. The 94 claims represented a significant reduction om the 137 the year before. Regarding adjudications, 986 claims have been dismiss , and 1,900 adjudicated. Awards are now up to $61 million, well under the amou appropriated for this fiscal year.

Dr. Jeff Evans then updated the Committee on the revision of the Vaccine I ury Table. The NVICP is in the final stages of publishing a final rule, which will have anges for DTP and MMR. Also, the Section 313 report has been evaluated; recomme ations regarding changes to cover the vaccines in that report will probably be pres ted at the next ACIP meeting.

Dr. Balbier said that a Boston appeals court ruled that parents have the rig to sue for their own suffering, over and above what they receive through the vaccine npensation program. Since the program has no statute prohibiting any parent from d g this, the program is considering adding such a statute.

Wrap-up Issues on the Scope of the Vaccines for Children Program

MMR dose #2

Drs. Fleming, Davis, DeBuono, and Gail King had drafted the following st ment of intent of the ACIP, with Dr. Orenstein's incorporated change (boldfaced; can be modified):

> It is the intent of the ACIP to recommend that the VFC program fo FY 96 provide second dose MMR to:

Footnote re DTaP

The final proposal for vote for the VFC program was the following:

> **The ACIP recommends that a footnote be included in the immunizati schedule stating that "The use of DTaP may be preferred for the 4th (for child ≥15 months of age) and 5th doses of the DPT series because it is likely to se fewer local reactions, fever, and other common systemic events than whole- DTP."**

Potential conflicts of interest for this vote were support from of financial int st in Lederle, Connaught, or the State health departments of Michigan and Mass husetts. The measure passed 6-0 [For: Drs. Clements, Ramirez-Ronda, Schoenbaun Jackson, Ward, and Davis; against: zero; Abstaining: Drs. Thompson, Halsey and E ards; Absent: DeBuono].

BCG Update

Dr. Halsey said that on April 29 the ACET and the ACIP working group on CG vaccine agreed to have a joint statement on the role of BCG vaccines in the trol of TB and embarked on a process of resolving their differences in the recomme ations. Dr. Halsey asked that comments on the draft statement and the additional t pages of changes be returned to him by July 15. In follow-up discussion, Dr. Snide greed to distribute the second meta-analysis results in the *International Journal of Ep miology* to all members.

National Vaccine Advisory Committee Report on Adult Immunization

Dr. Walter W. Williams briefly reported on this committee's report on adul immunization, issued in January 1994 and contained in the briefing book. e report describes the goals, strategies, and recommendations to address major issue at affect adult immunization in the United States.

Revision of the Varicella Statement and Status of Application for Licensure

Dr. Sandra Holmes briefly updated the revision of the ACIP varicella state t. Although the structure of the document was changed, the only substantive c nge was that, at HICPAC's request, the guidelines for HCWs have been clarified an xpanded. Comments should be returned by July 30 to Ms. Kovach.

Regarding the state of licensure, Dr. Jo White from Merck & Co, Inc., said everal questions concerning manufacturing and post-marketing surveillance are be ironed out this summer.

Hepatitis A Working Group Formed

The scheduled hepatitis A presentation was canceled, but Dr. Margolis aske or a working group to prepare for the fact that a licensed vaccine will be availab in the near future and some recommendations should be being prepared for its use Dr. Davis asked for volunteers for this working group. Its members will be Drs. Dav Edwards, Ward, Hall, Schaffner, Fleming, David Scheiffle and William Butler. Dr. I is also asked for advance copies of the ACIP developing document on this subject a l issues to be discussed be distributed before any subsequent meeting.

Status of Trials and Cost-Benefit Analysis of Rotavirus Vaccines

Dr. Roger Glass led off the first presentation to the ACIP on rotavirus--the jor cause of severe diarrhea in children worldwide. He said there is clearly a disease rden and a need for rotavirus vaccine. The issue of natural immunity to rotavirus is ry important, but immunity is not complete. There are no good animal model but there are candidate vaccines that are within two years of possibly being approved r widespread use.

Dr. Joe Carmardo from Wyeth then presented data from the studies of the esus tetravalent rotavirus vaccine developed by Dr. Kapikean (RRV-TV). He sa that this vaccine is safe and well tolerated, evidenced by the low rate of reactogenicit fever, diarrhea and vomiting. The vaccine is efficacious in preventing any avirus gastroenteritis and especially efficacious in preventing clinically severe disea

Next, Dr. Joe Eiden from Merck and Company profiled that manufacture quadravalent, bovine rotavirus vaccine. Results of a just completed trial a pending. In previous trials, it has been 64%-100% efficacious. Against clinically sign cant rotavirus diarrhea, it is 100% protective.

Dr. Paul H. Madore from American Cyanamid reported on Lederle-Praxis ological efforts to develop a rotavirus vaccine. The manufacturer hopes to have ph l studies soon.

Dr. Jean Smith described the epidemiologic features of rotavirus disease a presented a cost-benefit analysis, which showed that a rotavirus vaccination program is pected to yield a total savings to society of $466 million per year.

Influenza Antiviral Recommendations

Dr. Nancy Arden reviewed the final draft of the ACIP Recommendations the Prevention and Control of Influenza, Part II, Antiviral Agents. The Com ttee decided to replace the second sentence in the first paragraph on page 2, wi the following sentence: "Although there are no more data on the effectiveness

Issues on Scope of VFC for Vote by ACIP - 1

Vaccination to prevent hepatitis B virus (HBV) infectio in high risk groups

The ACIP working group on 'Scope of Vaccines for Childre 'rogram' proposes the following schedule and recommendations f use of vaccines to prevent HBV infection in persons ≤ 18 years : age in groups at high risk of HBV infection, as defined in M R 1991; 40:(RR-13);pp. 1-25 and MMWR 1990;39:(RR-2):pp.13.

1. Persons with occupational risk

Any health-care or public safety worker whose tas involve exposure to blood or blood-contaminated body fluid, ncluding persons in training before they have their first co act with blood.

2. Clients of institutions for the developmentally isabled

Clients in resident institutions for the devel mentally disabled, as well as clients who live in smaller r idential settings with known HBV carriers.

Classroom contacts of a developmentally disabled cla smate who is an HBV carrier who behaves aggressively or h special medical problems that increase the risk of exposure o his or her blood or serous secretions.

3. Hemodialysis patients

Susceptible hemodialysis patients and patients th renal disease that may result in dialysis. These patient are more likely to respond to the vaccine before init ation of dialysis.

4. Recipients of certain blood products

Patients who receive clotting-factor concentra s should receive hepatitis B vaccine as soon as facto placement becomes necessary.

5. Household contacts/sexual partners of HBV carr rs

All household and sexual contacts of persons ide ified as HBsAg positive.

6. Adoptees from countries where HBV infection is ndemic

Family members of adopted or foster children found be HBsAg positive.

Conclusions and recommendations are summarized with each topic below an are in an unlabeled tab in the briefing book.

Issue for Vote: Hepatitis B Vaccination

Dr. Hal Margolis went over the groups for whom hepatitis B vaccination is recommended and would be eligible for VFC. He said that the working gro recommended that all the following high-risk groups be included in the VFC hose with occupational risk; clients of institutions for the developmentally disabled; he dialysis patients; recipients of certain blood products; household contacts/sexual part rs of HBV carriers; family contacts of HBsAg-positive adoptees from countries wl e HBV infection is endemic; international travelers; injecting drug users; sexually a ve homosexual and bisexual men; sexually active heterosexual men and women th sexually transmitted diseases (STDs) or who are prostitutes and persons who ave sex with more than 1 partner in the last 6 months; inmates of jails; and children ss than 7 years old born to first-generation immigrant women from countries where H V infection is high.

Dr. Davis read the matter for vote:

> The ACIP recommends that hepatitis B vaccination for persons ≤18 ears of age in the risk groups identified above be included in the Vaccines fo Children program, and that hepatitis B vaccine should be given in the dosages id by the schedules described in the above paragraphs.

Potential conflicts of interest for this vote were support from or financial in est in Merck or SKB. The vote passed 3-0. (For: Drs. Ramirez-Ronda, DeBuon and Davis; 0, opposed; 5 abstaining; and 1 absent (Dr. Jackson).

Dr. Davis read the second item for vote:

> The ACIP recommends that universal vaccination of adolescents witl epatitis B vaccine should not be included in the Vaccines for Children Program t this time. The committee recommends that this issue be reconsidered after the CIP has reached agreement on the need for universal vaccination of adolesce in the context of revision of its recommendations for prevention of hepatiti infection.

Since Mr. Malone said it was not necessary to vote on a negative issue, the nsensus was not to vote on this issue.

Vaccination to prevent hepatitis B virus (HBV) infe tion of adolescents

The ACIP working group on 'Scope of Vaccines for Childre agreed that the VFC program should not currently include routine vaccination of adolescents other than those who are ider lfied to have defined risk factors noted above. The working gr p noted that the ACIP will be considering whether vaccination of l, or at least one cohort of, adolescents should be routinely reco ended at upcoming meetings. The working group recommended that i the ACIP does recommend universal vaccination of some or all ad escents, then the ACIP should reconsider whether the VFC progr should include some or all cohorts of adolescents.

Vote: **The ACIP recommends that universal vacci tion of adolescents with hepatitis B vaccine shou not be included in the Vaccines for Children progra at this time. The committee recommends this issue ould be reconsidered after the ACIP has reached agreem t on the need for universal vaccination of adolescen in the context of revision of its recommendations for evention of hepatitis B infection.**

Note: Kevin Malone suggests the ACIP does n need to formally vote on negative issues - which will esult in a vaccine or risk **not** being included in the Va cines for Children program. Therefore the ACIP may el t not to vote on this issue.

Vaccination with a second dose of MMR vaccine for mor than one cohort of children

The ACIP working group on 'Scope of Vaccines for hildren' **agreed that the VFC program for October 1994 shou** include **one cohort of children (≤18 years of age) to rece** e second **dose of MMR in each state,** as defined in the form vote on the MMR schedule at the February 23-24 ACIP meet g. **They recommended that VFC should also include vaccinat** n of any **eligible children (≤18 years of age) who are requir** by state **laws or state university or college Regents p** icies to **receive a second dose of MMR or measles vaccin** prior to **attendance in schools or colleges.**

The working group agreed that for the FY 1996 year beginning October, 1995), the VFC program should be expanded o provide the second dose of MMR vaccine to two cohorts of ildren in each state, in addition to those whose vaccination required by state law or Regent's policy. This policy was commended to assure that more rapid immunization of school ildren is completed in order to reach the zero indigenous m sles goal for the year 2000. Working group members conclude that this anticipated expansion of coverage for second dos MMR would allow states to better plan implementation for th 1995-1996 school year.

Vote: **The ACIP recommends that the VFC program for (tober 1994 should include one cohort of children (≤18 ye s of age) to receive second dose of MMR in each state, nd should include vaccination of any eligible childrer ≤18 years of age) who are required by state law: or state university or college Regents policies to receive a second dose of MMR or measles vaccine prior t attendance in schools or colleges.**

Vote: **The ACIP recommends that for the FY 1996 yea: (beginning October, 1995), the VFC program should be panded to provide second dose of MMR vaccine to two ohorts of children in each state, in addition to ose whose vaccination is required by state law or Rege 's policy.**

Note: We have the option to vote on he second resolution now, or to defer a vote until ne year.

Vaccination with pneumococcal polysaccharide vaccine for] rsons in high risk groups

The ACIP working group on 'Scope of Vaccines for ıildren' agreed that the VFC program for October 1994 shoul include pneumococcal vaccination of children (≤ 18 years c age) in high risk groups defined in the ACIP recommendation: entitled "Pneumococcal polysaccharide vaccine" (1989 p.3), ınd that this recommendation would include revaccination f those groups for which that is recommended.

Children and adolescents in the following g: ıps are recommended for vaccination:

1. Children ≥ 2 years old with illnesses assoc: ıed with increased risk of pneumococcal disease or its complications: examples include anatomic or nctional asplenia, including sickle cell disease; ephrotic syndrome; cerebrospinal fluid leaks; congen: al heart disease; cirrhosis; end-stage renal disease; severely compromising pulmonary disease (such as cystic brosis), and conditions with immunosuppression ncluding leukemia, lymphoma, aplastic anemia, g eralized malignancy or therapy with alkylating agents, antimetabolites, radiation or large am ınts of corticosteroids).

   Note: Most of the groups listed above are lis ed in the current ACIP recommendations under children at igh risk. However, certain groups are not explicitly li ed there (see underlined groups above), but are implie or listed under high risk adults (including congen: al heart disease, cirrhosis, end-stage renal disease, ıd severe chronic pulmonary disease). All members of t e working group discussed and recommended inclusion of irrhosis, renal disease, and congenital heart disease a the June 8 meeting and in follow-up conversations. H vever, at the time of the meeting, the group did n discuss inclusion of severe pulmonary diseases such ıs cystic fibrosis (it did exclude asthma and chronic b: ıchitis). In subsequent discussion, most members favore inclusion of this group. None of these as relativel strictly defined here would be overwhelming in number but data on disease risk in these groups appear to be imited.

2. *Children ≥ 2 years with asymptomatic or sympto tic human immunodeficiency virus (HIV) infection.*

3. *Persons ≥ 2 years living in special environme s with an identified increased risk of pneumococcal dis ıse or its complications (e.g. certain Native American po lations).*

Primary vaccination consists of a single dose of pn mococcal 23-valent vaccine.

Revaccination should be strongly considered for p sons who received the 14-valent vaccine who are at highes risk of fatal pneumococcal infection (asplenic patients) and for those who received the 23 valent vaccine ≥ 6 years fore who have rapid decline in pneumococcal antibody levels patients with nephrotic syndrome, renal faillure, or ansplant patients). Revaccination after 3-5 years should be nsidered for children with nephrotic syndrome, asplenia, or s kle cell anemia who would be ≤ 10 years old at revaccinatio

It was estimated that this expansion of the C would potentially provide vaccine to about 300,000 childr at risk.

Vote: The ACIP recommends that pneumococcal vacc ation of children (≤18 years of age) at high risk of thi disease, as defined above, be included in the Va ines for Children program. The schedule and d age for vaccination should be those defined above.

Vaccination with influenza vaccine for persons in high r sk groups

The ACIP working group on 'Scope of Vaccines for hildren' agreed that the VFC program for October 1994 ould not include influenza vaccination of children at hi risk of complications of influenza disease.

The working group recommended that influenza vacci tion for persons in high risk groups should be added to the rogram in FY 1996. The working group noted that this rec mendation would potentially apply to as many as 8-9 millio children, most of whom had asthma or chronic bronchitis; tha it would pose a substantial new burden to implement during the first year of the VFC program, particularly for provider recruitment; that no Federal contract is currentl in place for influenza vaccine and that it is unlikely t such a contract could be developed for the 1994 fall influenza season. Implementation of a recommendation in the cond year of VFC would allow time for both CDC staff and states to better prepare to implement this recommendation. e working group recommended that vaccination of contacts of ersons at high risk of influenza not be included in e future recommendation until the approximate numbers of s h persons could be better estimated.

Vote: The ACIP recommends that the VFC program for C ober 1994 should not include influenza vaccination of ildren at high risk of complications of influenza dise e.

Note: Kevin Malone suggests the ACIP does t need to formally vote on negative issues - which wil result in a vaccine or risk group not being inclu d in the Vaccines for Children program. Therefore t ACIP may elect not to vote on this issue.

Vote: The ACIP recommends that influenza vacc: ation for persons in high risk groups should be added o the VFC program in FY 1996.

Note: The Options here are (1) to not vote o this issue until 1995; (2) to vote to accept t ; general recommendation, with a stipulation that e precise groups to be included in the program will b determined in a separate vote next year; or (3) draft a resolution which explicitly defines those g ups to be included now.

7. International travelers

Persons who will spend more than 6 months in areas ith high rates of HBV infection and who will have close co act with the local population, and short-term travelers who e likely to have contact with blood (e.g.,in a medical s ting) or sexual contact with residents of areas with high or intermediate levels of endemic disease.

8. Injecting Drug Users

All injecting drug users.

9. Sexually active homosexual and bisexual men

Sexually active homosexual and bisexual men.

10. Sexually active heterosexual men and women

Men and women who are diagnosed as having recentl acquired other sexually transmitted diseases, prostitutes, a d persons who have a history of sexual activity with mor than one partner in the previous 6 months, including patie s seen in clinics for sexually transmitted diseases.

11. Inmates of long-term correctional facilities

Inmates in long-term correctional facilities.

12. Children less than 7 years of age born to first eneration immigrant women from countries where HBV infection s of high or intermediate endemicity

All children < 7 years of age living in these fa lies. For purposes of this resolution this is interpret to mean children born after October 1, 1987.

The following footnotes and text clarify these recomme ations:

The recommended dosages for hepatitis B vacci ation for children and adolescents in these groups are as f lows:

Abstract table 3 from 1991 recommendations

The recommended intramuscular, three dose vaccinat a schedule may vary for children and adolescents to take into ccount the feasibility of delivering the three doses of vac ne over a given period of time. Hepatitis B vaccines re highly immunogenic over a wide variety of schedules. Ho ver, there should be a minimum of one month between the firs and second dose, and a minimum of 2 months between the seco and third

Contraindications to Childhood Vaccines - adapted from cu rent ACIP statements

Vaccines to prevent Diphtheria-tetanus-pertussis

The following conditions are contraindications to admini: cation of additional doses of vaccines containing DTP or DTaP:

1. An immediate anaphylactic reaction.

2. Encephalopathy (not due to another identifiab] cause), defined as an acute, severe, central nervous syste disorder occurring within 7 days after vaccination and generally consisting of major alterations in cons lousness, unresponsiveness, or generalized or focal sei: res that persist more than a few hours, without recovery within 24 hours.

The following are considered precautions (war: ngs) to administration of additional doses of vaccines contair ig DTP or DTaP. If any of the following events occurs in tempor: relation with the receipt of either whole cell DTP or DTaP, the cision to administer subsequent doses of vaccine containing the pertussis component should be carefully considered. Ther may be circumstances, such as high incidence of pertussis, i: which the potential benefits outweigh the possible risks.

1. Temperature of ≥ 40.5 C (105 F) within 48 hours, ot due to another identifiable cause.

2. Collapse or shock-like state (hypotonic-hyp esponsive episode) within 48 hours.

3. Persistent, inconsolable crying lasting ≥ 3 hours occurring within 48 hours.

4. Convulsions with or without fever, occurring with 1 3 days.

If these events occur after receipt of any of the first four doses of whole-cell DTP vaccine and if additional doses o pertussis vaccine are indicated because the potential benefits c weigh the potential risks, consideration should be given to the se of DTaP for the fourth and fifth doses.

The following text provides additional information egarding vaccination with DTP, DTaP, or DT for children with eac of these conditions:

Contraindications

If any of the following events occur in temporal relat nship to the administration of DTP, further vaccination wi DTP is contraindicated. Because no data currently exist suggest otherwise, contraindications to further doses of DTaP a the same as those for the whole-cell DTP:

1. An immediate anaphylactic reaction. Because of unc tainty as to which component of the vaccine might be respc ible, no further vaccination with any of the three antig s in DTP should be carried out. Alternatively, such individ ls may be referred for evaluation by an allergist and deser itized to tetanus toxoid if specific allergy can be demonst: ted.

2. Encephalopathy (not due to another identifiable ca e). Even though causation by DTP or DTaP cannot be estal lished, no subsequent doses of pertussis vaccine should be giv n. It may be desirable to delay for months before adminis ering the balance of the doses of DT necessary to complete e primary schedule.

Precautions (Warnings)

If any of the following events occur in temporal lation to receipt of DTP or DTaP, the decision to give subseque doses of vaccine containing the pertussis component should b carefully considered. There may be circumstances, such as high i cidence of pertussis, in which the potential benefits outweigh t possible risks, particularly because these events are not assc ated with permanent sequelae. The following events are considered precautions:

1. Temperature of ≥ 40.5 C (105 C) within 48 hours not due to another identifiable cause. Because such febri reactions are usually attributed to the pertussis component, accination with DT should not be discontinued.

2. Collapse or shock-like state (hypotonic-hy responsive episode) within 48 hours. Although these uncommon vents have not been recognized to cause death nor to indu permanent neurologic sequelae, it is prudent to continue accination with DT, omitting the pertussis component.

3. Persistent inconsolable crying lasting ≥ 3 hour occurring within 48 hours.

4. Convulsions with or without fever occurring witl 1 3 days. Although a convulsion following DTP vaccination has reviously been considered a contraindication to further d es, under certain circumstances subsequent doses may be ndicated, particularly if the risk of pertussis in the c munity is high. If a child has a seizure following the firs or second dose of DTP, it is desirable to delay subsequent ses until the child's neurologic status is better defined. T vaccine should not be administered before a decision ha been made about whether to restart the DTP series. Regardle s of which vaccine is given, it is prudent to administer ace minophen, 15 mg/kg body weight, at the time of vaccination id every 4 hours subsequently for 24 hours.

If these events occur after receipt of any of the first four doses of whole-cell DTP vaccine and if additional doses o pertussis vaccine are indicated because the potential benefits c weigh the potential risks, consideration should be given to the se of DTaP for the fourth and fifth doses.

The following text provides additional clarification r arding DTP vaccination of infants and young children who have underlying neurologic disorders:

Whether and when to administer DTP to children wit proven or suspected underlying neurologic disorders must be de ded on an individual basis. Important considerations include ne current local incidence of pertussis, the near absence of dip heria, and the low risk of tetanus in the U.S.. On the bas of these considerations and the nature of the child's di rder, the following approaches are recommended:

1. **Infants and children with previous convulsions.** A ng infants and children with a history of previous seiz es, it is prudent to delay DTP vaccination until the child' status has been fully assessed, a treatment regimen establis ed, and the condition stabilized. However, delaying DTP vacci tion until the second 6 months of life will increase the ris of febrile seizures among persons who are predisposed. When TP or DT is given, it is prudent to administer acetaminoph , 15 mg/kg body weight, at the time of vaccination and e ry 4 hours subsequently for 24 hours.

2. **Infants as yet unvaccinated who are suspecte of having underlying neurologic disease.** It is prude to delay initiation of vaccination with DTP or DT (bu not other vaccines) until further observation and study ha e clarified the child's neurologic status and the effect c treatment. The decision as to whether to begin vaccination w h DTP or DT should be made no later than the child's first b thday.

3. **Children who have not received a complete series** **vaccine** and who have a neurologic event occurring between **ses.** If the seizure or other disorder occurs before the firs birthday and before completion of the first three doses of t primary series of DTP, further doses of DTP or DT should b deferred until the infant's status has been clarified. Th decision whether to use DTP or DT to complete the series shou be made no later than the child's first birthday, and should take into consideration the nature of the child's proble and the benefits and possible risks of the vaccine. If the eizure or other disorder occurs after the first birthday, t child's neurologic status should be evaluated to ensure th disorder is stable before a subsequent dose of DTP is giver

4. **Infants and children with stable neurologic** **nditions.** Infants and children with stable neurologic nditions, including well-controlled seizures, may be ccinated. Parents of infants and children with histories of nvulsions should be informed of the increased risk of post ccination seizures. Acetaminophen (dose 15 mg/kg body weig , at the time of vaccination and every 4 hours subsequen y for 24 hours) should be given to children with such hi tories to reduce the possibility of postvaccination fever.

Vote: **The ACIP recommends that the contraindic ions and precautions for use of vaccines containing D and DTaP specified above, with the specific clarificat ns listed above, be included in the Vaccines for Childre program.**

Vaccines which contain diphtheria toxoid and tetanus to id

The following are contraindications to receipt of dit tional doses of diphtheria toxoid or tetanus toxoid nta ining vaccine:

1. Severe hypersensitivity reaction (anaphylaxis)

   If an anaphylactic reaction to a previous dose tetanus toxoid is suspected, intradermal testing with app priately diluted tetanus toxoid may be useful before a decisi is made to discontinue tetanus toxoid vaccination

2. Neurologic reaction to a previous dose - **(NOTE: T S IS NEW LANGUAGE DEVELOPED IN RESPONSE TO THE IOM REPORT ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES; SEE A O TUTTLE MEMO)**

   A previous episode of Guillain-Barre syndrome (GBS) ith onset within 6 weeks following receipt of a tetanus- ntaining vaccine is a contraindication to additional doses tetanus-containing vaccine.

   The existence of only one case report of repeated isodes of GBS following receipt of tetanus-containing vaccine suggests such individuals may be quite rare.

The following are precautions to receipt of diphtheria d tetanus toxoid containing vaccines:

1. High fever or Arthus-type hypersensitivity to previ s dose of tetanus-containing vaccine

   Persons who experienced Arthus-type hypersensitivit reactions or a temperature of > 103 F (39.4 C) following a pr r dose of tetanus toxoid usually have high serum tetanus antitoxin levels and should not be given emergency doses d more frequently than every 10 years, even if they have a ound that is neither clean nor minor.

Vote: **The ACIP recommends that the contraindic icns and precautions for use of diphtheria and tet us toxoid containing vaccines as specified above be inc ded in the Vaccines for Children program.**

Vaccines to prevent Measles-Mumps-Rubella (MMR)

The following conditions are contraindications to adminis :ation of MMR vaccine, or vaccines which contain one or mo: of its components:

1. Pregnancy
2. History of anaphylactic reactions to egg ingestio (MMR and any measles or mumps containing vaccines)
3. History of anaphylactic reaction to neomycin
4. Known altered immunocompetence
5. Moderate or severe illness with or without fever

The following are considered precautions to administra on of MMR (or component) vaccines:

1. Thrombocytopenia
2. Recent receipt of immune globulin (up to 3 months r longer)

The following text provides additional information regarding vaccination with MMR or component vaccines with eac of these conditions:

Contraindications

1. Pregnancy. Because of the theoretical risk to ne fetus, women of childbearing age should receive MMR or it component vaccines only if they state they are not pregna : and are counseled not to become pregnant for 3 mo hs after vaccination (or at least 30 days after monoval t measles vaccine). Reasonable practices in an immunizat n program include 1) asking women if they are pregnant, 2 excluding those who state they are, 3) explaining the ieoretical concern about risk for the fetus to the othe , and 4) explaining the importance of not becoming pregnant during the 3 months following vaccination (this interval s uld be 30 days after monovalent measles vaccine). If a pre iant woman is vaccinated or if a woman becomes pregnant with 1 3 months after vaccination, she should be counseled bout the theoretical concern for the fetus, but MMR or mea es, mumps or rubella vaccination during pregnancy should not ordinarily be a reason to consider interruption of pregnancy

2. History of anaphylactic reaction to egg ingestion. Persons with a history of anaphylactic reactions (ge ralized urticaria or hives, swelling of the mouth and throat, difficulty breathing [wheezing], hypotension or sho .) after egg ingestion should be vaccinated only with caut n using published protocols. Evidence indicates that persor are not at increased risk if they have egg allergies that are not anaphylactic in nature. A history of anaphy xis or anaphylactic-like reactions to egg ingestion i not a contraindication to mono-component rubella vaccine.

3. History of anaphylactic reaction to neomycin. Pe ons who have experienced anaphylactic reactions to topi ally or systemically administered neomycin should not recei MMR or any of its component vaccines. A history of contact dermatitis to neomycin is not a contraindication to eceiving these vaccines.

4. Altered immunocompetence

Replication of vaccine viruses can be enhanced in pe ons with immune deficiency diseases and in persc with immunosuppression, as occurs with congenital immunode iciency, leukemia, lymphoma, generalized malignancy, or resu ing from therapy with alkylating agents, antimetabolites, rad tion, or large doses of corticosteroids. Such persons shou not be given live virus vaccines, including MMR and ea of its component vaccines - except persons with nfection (symptomatic or asymptomatic) with human immunodefi cy virus infection (HIV), who can receive MMR.

Asymptomatic HIV-infected persons in need of M should receive it. MMR vaccine should be considered for all symptomatic HIV-infected persons, including childrer iagnosed with AIDS.

Patients with leukemia in remission whose chemot rapy has been terminated at least 3 months may be vaccinated with live virus vaccines.

Steroid therapy usually does not contraindicate admi stration of live-virus vaccines when such therapy is short erm (< 2 weeks); low to moderate dose; long-term, alte iate day treatment with short-acting preparations; ma itainance physiologic doses (replacement therapy); or ad nistered topically (eyes or skin), by aerosol, or by intra- ticular, bursal or tendon injection. The exact amount of sy emically absorbed corticosteroids and the duration of admi stration needed to suppress the immune system of an otherwi healthy child are not well defined. The imunosuppressive ffects of steroid treatment vary, but many clinicians consi r a dose equivalent to either 2 mg/kg of body weight or a t al of 20

mg/day of prednisone as sufficiently immunosuppı ssive to raise concern about the safety of immunization with ve-virus vaccines. Physicians should wait at least 3 moı ıs after discontinuation of therapy before administering a ve-virus vaccine to patients who have received high-dose, sy emically absorbed steroids for ≥ 2 weeks.

Precautions

1. Thrombocytopenia. Children with a previous histor of acute idiopathic thrombocytopenia purpura or low platelet evels at the time of vaccination may be at increased isk for clinically significant thrombocytopenia following MI vaccine. **(NOTE: THIS IS NEW LANGUAGE ADDED IN RESPONSE ' THE IOM REPORT; SEE TUTTLE MEMO)**

2. Blood and other antibody containing blood products, ncluding immune globulin (IG) preparations, can diminish e immune response to MMR or its individual component vaccine . MMR or its component vaccines should be given at least 2 we ts before the administration of an immune globulin (IG) ontaining product or deferred until 3 or more mon s after administration of such preparations. High doses f immune globulin can inhibit the immune response to measl ; vaccine for more than 3 months. Administration of immune g. oulin can also inhibit the response to rubella vaccine. The effect of IG preparations on response to mumps vaccine is ur nown, but commercial IG preparations contain antibodies to t is virus.

   Therefore, after an immune globulin containing pre ration is received, these vaccines should not be administered efore the interval recommended in table 1. If administra on of an immune globulin preparation becomes necessary cause of imminent exposure to disease, MMR or its compone vaccines can be administered simultaneously with the immu globulin preparation, although vaccine-induced immunit may be compromised. Unless specific serologic testing ind ates that specific antibodies have been produced, vaccinatic should be repeated after the recommended interval.

Vote: **The ACIP recommends that the contraindic ions and precautions for use of MMR and measles, mumps d rubella containing vaccines specified above, with t specific clarifications listed above, be included in t Vaccines for Children program.**

Table 1. Suggested intervals between administration of immune globulin preparations for variou ıdications and vaccines containing live measles virus.*

Indications	Dose (including mg IgG/kg)	Suggested interva fore measles vaccinatic months)
Tetanus (TIG)	250 units (10 mg IgG/kg) IM	3
Hepatitis A (IG)		
Contact prophylaxis	0.02 mL/kg (3.3 mg IgG/kg) IM	3
International travel	0.06 mL/kg (10 mg IgG/kg) IM	3
Hepatitis B prophylaxis (HBIG)	0.06 mL/kg (10 mg IgG/kg) IM	3
Rabies immune globulin (HRIG)	20 IU/kg (22 mg IgG/kg) IM	4
Varicella prophylaxis (VZIG)	125 units/10 kg (20-40 mg IgG/kg) IM (maximum 625 units)	5
Measles prophylaxis (IG)		
Normal contact	0.25 mL/kg (40 mg IgG/kg) IM	5
Immunocompromised contact	0.50 mL/kg (80 mg IgG/kg) IM	6
Blood transfusion:		
Red blood cells (RBC's), washed	10 mL/kg (negligible IgG/kg) IV	0
RBC's, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3
Packed RBC's (Hct 65%)+	10 mL/kg (60 mg IgG/kg) IV	6
Whole blood (Hct 35-50%)+	10 mL/kg (80-100 mg IgG/kg) IV	6
Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7
Replacement of humoral Immune deficiencies	300-400 mg/kg IV# (as IGIV)	8
Treatment of:		
ITP**	400 mg/kg IV (as IGIV)	8
ITP**	1000 mg/kg IV (as IGIV)	10
Kawasaki disease	2 grams/kg IV (as IGIV)	11

* This table is not intended for determining the correct indications and dosage for the use (nmune globulin preparations. Unvaccinated persons may not be fully protected against measles during th ntire suggested interval and additional doses of immune globulin and/or measles vaccine may be indicated lowing measles exposure. The concentration of measles antibody in a particular immune globulin preparation c vary by lot. The rate of antibody clearance following receipt of an immune globulin preparation can also vary. e recommended intervals are extrapolated from an estimated half-life of 30 days for passively acquired antibo(ınd an observed interference with the immune response to measles vaccine for 5 months following a dose of mg IgG/kg (37).

+ Assumes a serum IgG concentration of 16 mg/ml.

Measles vaccination is recommended for children with HIV infection but is contraindicat in patients with congenital disorders of the immune system.

** Immune (formerly, idiopathic) thrombocytopenic purpura.

Vaccines to prevent Poliomyelitis

Oral Polio Vaccine

The following conditions are contraindications to adminis ation of oral polio vaccine:

1. Immunodeficiency or altered immunocompetence
2. Infection with HIV or household contact with HIV
3. Immunodeficient household contact

The following condition is a precaution to administrati of oral polio vaccine

1. Pregnancy

The following text provides additional information egarding vaccination with OPV for persons with any of these cond ions:

Contraindications

1. Immunodeficiency or altered immunocompetence.

   Patients with immunodeficiency diseases, such a combined immunodeficiency, hypogammaglobulinemi , and agammaglobulinemia, should not be given OPV becaus of their substantially increased risk of vaccine-associate disease. Patients with altered immune states due to diseas such as leukemia, lymphoma, or generalized malignancy, or w ch immune systems compromised by therapy with cortic steriods, alkylating drugs, antimetabolites, or radiation ould not receive OPV because of the theoretical risk of paralytic disease. Enhanced IPV is recommended for suc persons. Although a protective response to IPV in the immunoc mpromised cannot be assured, the vaccine is safe and may fer some protection.

2. Persons with HIV infection or household contact with HIV infection.

   Although OPV has not been harmful when admin tered to asymptomatic HIV-infected children, IPV is the ccine of choice for a child who is known to be infected. valuation and testing for HIV-infection of asymptomatic child n are not necessary before decisions regarding immunization ith polio vaccines are made. **(Note: Current ACIP recomendati s are not explicit with regard to vaccination of household ntacts of**

HIV-infected (but not immunocompromised) children. However, the AAP Red Book is explicit (these contacts shou receive IPV), and CDC staff agree with that recommendati 1. This issue will be brought up in discussions about th new ACIP polio prevention recommendations)

3. Immunodeficient household contacts.

OPV should not be used for immunization of househol contacts of immunodeficient patients; IPV is recommended. f OPV is inadvertantly administered to a household-type cor ct of an immunodeficient patient, close contact between the p cient and the recipient of OPV should be avoided for appro mately 1 month after vaccination. Because of the poss: ility of immunodeficiency in other children born to a famil in which there has been one such case, OPV should not be ven to a member of a household in which there is a family story of immunodeficiency until the immune status of the rec pient and other children in the family is documented.

Precautions

1. Pregnancy. It is prudent on theoretical ground to avoid vaccinating pregnant women. However, if immediate otection against poliomyelitis is needed, OPV is recommende .

Inactivated polio vaccine

The following conditions are contraindications to adminis ation of inactivated polio vaccine (IPV):

1. Anaphylactic reaction to streptomycin or neomycin

   Persons who have had anaphylactic reactions to to cally or sytemically administered streptomycin and neomycin ould not receive enhanced-potency IPV.

The following condition is a precaution to administrati of IPV:

1. Pregnancy

   On theoretical grounds, it is prudent to avoid v cinating pregnant women.

Vote: **The ACIP recommends that the contraindica ons and precautions for use of OPV and IPV specified a ve, with the specific clarifications listed above, be i cluded in the Vaccines for Children program.**

Vaccines to prevent Hepatitis B virus infection

The following condition is a contraindication to adminis ation of additional doses of hepatitis B vaccine.

1. Anaphylactic reaction to a previous dose of he atitis B vaccine.

   Further vaccination with hepatitis B va ine is contraindicated in persons with a history of anaph axis (or severe reaction) after a previous dose of hepatitis vaccine.

Vote: **The ACIP recommends that the contraindication or use of hepatitis B vaccine specified above be inclu d in the Vaccines for Children program.**

Vaccines to prevent invasive Haemophilus influenza type b infection

The following condition is a contraindication to admini ration of additional doses of conjugate H. influenza vaccine (c vaccines which contain Hib conjugate antigens)

1. Anaphylactic reaction to a previous dose of a sp ific Hib conjugate vaccine

   Vaccination with a specific Hib conjugate v ccine is contraindicated in persons knowns to have e perienced anaphylaxis following a prior dose of that vacci .

   Contraindications and precautions for the use of co ined DTP-Hib vaccines or other Hib vaccines for combined in ction are the same as those for its individual component va ines.

Vote: **The ACIP recommends that the contraindication or use of Haemophilus influenza type b conjugate vaccine specified above be included in the Vaccines for Childre program.**

Vaccines to prevent pneumococcal infection

The following condition is a precaution to administ ıtion of pneumococcal vaccine

1. Pregnancy

   The safety of pneumococcal vaccine for pregnant wor ı has not been evaluated. Ideally women at high risk of pn ımococcal disease should be vaccinated before pregnancy.

Vote: **The ACIP recommends that the precaution f use of pneumococcal polysaccharide vaccine specifie above be included in the Vaccines for Children progran**

All vaccines

The following conditions are contraindications to admini: ration of any childhood vaccine

1. Anaphylactic reaction to the vaccine or a constitu nt of the vaccine.

2. Moderate or severe illnesses with or without feve:

   Vaccination of persons with moderate or severe illn s with or without fever should generally be deferred until hey have recovered.

Vote: **The ACIP recommends that the contraindications or use of vaccines as specified above be included in t Vaccines for Children program.**

Table from Standards for Pediatric Immunization Prac ices and
General Recommendations on Immunization - for reference/i ormation

Table 2.

Guide to contraindications and precautions to vaccinations+

Vaccine	True contraindications and precautions		Not contraindications (may be administered)	ccines
GENERAL FOR ALL VACCINES [DTP/DTaP, OPV, IPV, MMR, Hib, Hepatitis B]	Anaphylactic reaction to a vaccine contraindicates further doses of that vaccine		Mild to moderate local reaction (s swelling) following a dose of an i	ess, redness, able antigen
	Anaphylactic reaction to a vaccine constituent contraindicates the use of vaccines containing that substance			
	Moderate or severe illnesses with or without a fever		Mild acute illness with or without	-grade fever
			Current antimicrobial therapy	
			Convalescent phase of illnesses	
			Prematurity (same dosage and ind normal, full-term infants)	ons as for
			Recent exposure to an infectious	se
			History of penicillin or other non family history of such allergies	ific allergies or
DTP/DTaP	Encephalopathy within 7 days of administration of previous dose of DTP		Temperature of $<40.5^{\circ}C$ ($105^{\circ}F$) dose of DTP	owing a previous
	Precaution*	Fever of $\geq 40.5^{\circ}C$ ($105^{\circ}F$) within 48 hrs after vaccination with a prior dose of DTP	Family history of convulsions**	
		Collapse or shocklike state (hypotonic-hyporesponsive episode) within 48 hrs of receiving a prior dose of DTP	Family history of sudden infant	syndrome
		Seizures within 3 days of receiving a prior dose of DTP** time)	Family history of an adverse eve administration	llowing DTP
		Persistent, inconsolable crying lasting ≥ 3 hrs, within 48 hrs of receiving a prior dose of DTP		
OPV***	Infection with HIV or a household contact with HIV		Breast feeding	
	Known altered immunodeficiency (hematologic and solid tumors; congenital immunodeficiency; and long term immunosuppressive therapy)		Current antimicrobial therapy	
	Immunodeficient household contact		Diarrhea	
	Precaution*	Pregnancy		

Table 2 (continued).

Guide to contraindications and precautions to vaccinations+

Vaccine	True contraindications and precautions		Not contraindications may be administered)
IPV	Anaphylactic reaction to neomycin or streptomycin		
	Precaution*	Pregnancy	
MMR***	Anaphylactic reactions to egg ingestion and to neomycin****		Tuberculosis or positive PPD
	Pregnancy		Simultaneous TB skin testing***
	Known altered immunodeficiency (hematologic and solid tumors; congenital immunodeficiency; and long term immunosuppressive therapy)		Breast feeding
			Pregnancy of mother of recipient
	Precaution*	Recent immune globulin administration (see Table 8)	Immunodeficient family member
			Infection with HIV
			Nonanaphylatic reactions to egg
Hib	None identified		History of Hib disease
Hepatitis B	Anaphylactic reaction to common baker's yeast		Pregnancy

+This information is based on the recommendations of the Advisory Committee on Immunization Practices (ACI Committee on Infectious Diseases (Red Book Committee) of the American Academy of Pediatrics (AAP). Someti recommendations vary from those contained in the manufacturer's package inserts. For more detailed informatio consult the published recommendations of the ACIP, AAP, and the manufacturer's package inserts.

*The events or conditions listed as precautions, although not contraindications, should be carefully reviewed. Th administering a specific vaccine to an individual under the circumstances should be considered. If the risks are b the benefits, the vaccination should be withheld; if the benefits are believed to outweigh the risks (for example, d foreign travel), the vaccination should be administered. Whether and when to administer DTP to children with p underlying neurologic disorders should be decided on an individual basis. It is prudent on theoretical grounds to pregnant women. However, if immediate protection against poliomyelitis is needed, OPV is preferred, although considered if full immunization can be completed before the anticipated imminent exposure.

**Acetaminophen given before administering DTP and thereafter every 4 hours for 24 hours should be considere personal or with a family history of convulsions in siblings or parents.

***No data exist to substantiate the theoretical risk of a sub-optimal immune response from the administration of within 30 days of each other.

****Persons with a history of anaphylactic reactions following egg ingestion should be vaccinated only with cau been developed for vaccinating such persons and should be consulted. [J Pediatr 1983;102:196-9, J Pediatr 1988

*****Measles vaccination may temporarily suppress tuberculin reactivity. If testing cannot be done the day of M test should be postponed for 4-6 weeks.

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