DEPARTMENT OF HEALTH AND HUMAN SERVI ES

PUBLIC HEALTH SERVICE

CENTERS FOR DISEASE CONTROL AND PREVEN ION

Minutes of Meeting

ADVISORY COMMITTEE ON IMMUNIZATION PRAC ICES
October 19 & 20, 1994

Atlanta, Georgia

ADVISORY COMMITTEE ON IMMUNIZATION PRACT ES
Centers for Disease Control and Prevention
October 19-20, 1994 - Auditorium A

:30 AM	Introduction	Dr. J. D Dr. D. S er
9:00 AM	Immunization Coverage in the United States	Ms. E. Z
9:30 AM	Varicella Vaccine Update	Dr. S. E nes Dr. J. W e
10:00 AM	Vaccine Safety Update	Dr. B. C Dr. Glas
10:30 AM	**BREAK**	
11:00 AM	Revision of ACIP Recommendations Based on Findings of the Institute of Medicine Report on Vaccine Safety	Dr. B. (n Dr. J. T e
11:45 AM	Update on Vaccine Schedule Simplification	Dr. J. G ler Dr. S. H er
12:30 PM	LUNCH	
1:45 AM	Update on Vaccine Schedule Simplification continued	Dr. J. G ler Dr. S. H er
2:00 PM	Revision of the Meningococcal Vaccine Recommendation	Dr. J. W ger
2:15 PM	Review of Draft Recommendation on BCG	Dr. N. E ey
2:35 PM	Revision of Polio Vaccination Recommendations	Dr. R. S er
3:35 PM	BREAK	
3:45 PM	Status of Development of New Combination Vaccines (Manufacturers Reports)	Dr. J. H el Lederle Dr. B. H e SmithK e Beecham Dr. C. M chievitz Connau t Dr. D. V t Dr. J. W e Merck
4:45 PM	ACIP Policies on "Catch-Up" Vaccinations	Dr. S. S enbaum Harvar Hlth. Plan

5:15 PM	Update on the Status of the Vaccines for Children Program	Dr. J. C lero
5:45 PM	Vaccination of Health Care Workers	Dr. R. S kas
6:15 PM	**ADJOURN**	

October 20

8:30 AM	Adolescent and Adult Immunizations	Dr. A. E er AMA Dr. N. I sey Johns pkins Univ. Dr. R. S er Dr. P. G dner ACP Dr. W. V liams
9:45 AM	Revised Recommendations for Hepatitis B Vaccination	Dr. H. N golis
10:45 AM	The Need for ACIP Recommendations on Immunization Practices: Immunization Linkage with WIC	Dr. E. I es Mr. S. C nett USDA Dr. S. H hins Dr. C. L aron
11:45 AM	**BREAK**	
12:30 PM	Recommendations for Prevention of Hepatitis A: Hepatitis A Vaccine and Immune Globulin	Dr. C. S piro
1:45 PM	Worldwide Diphtheria Outbreaks	Dr. I. H ly
2:00 PM	National Vaccine Program Update	Dr. G. F inovich
2:15 PM	Update on Injury Compensation Program	Dr. L. B
2:30 PM	Public Comment	
2:45 PM	**ADJOURN**	

ATTENDEES:

COMMITTEE MEMBERS PRESENT
Dr. Jeffrey Davis (Chair)
Dr. Barbara Ann DeBuono
Dr. Kathryn Edwards
Dr. Marie Griffin
Dr. Fernando Guerra
Dr. Neal Halsey
Dr. Rudolph Jackson
Dr. Steve Schoenbaum
Dr. F. Thompson
Dr. Joel Ward

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

Liaison Representatives
Dr. William Butler (DOD)
Dr. Richard Clover (ATPM)
Dr. Thomas Copmann (PhRMA)
Dr. David Fleming (HICPAC)
Dr. Pierce Gardner (ACP)
Dr. William Glezen (IDSA)
Dr. Caroline B. Hall (AAP)
Dr. Edward Mortimer (AMA)
Dr. Kristin Nichol (VA)
Dr. Georges Peter (AAP)
Dr. William Schaffner (AHA)
Dr. David Scheiffle (NACI)
Dr. Richard Zimmerman (AAFP)

Acting Executive Secretary
Dr. Dixie Snider

Officer of the Director
Heidi Steele

Office of the General Counsel
Mr. Kevin Malone

Office of Health and Safety
Olivia Huggins

Office of Public Affairs
Kay Golan

National Center for Infectio Diseases
Dr. Miriam Alter
Scott Dowell
Dr. James Hughes
Dr. Frank Mahoney
Dr. Harold Margolis
Dr. Joseph McDade
Dr. Gary Sanden
Dr. Craig Shapiro
Gary Schatz

National Center for Preventi Services
Rosamond Dewart

National Immunization Prog n
Elias Avery
Dr. William Atkinson
Dr. Francisco Averhoff
Dr. Bob Chen
Dr. Jose Cordero
Dr. Vance Dietz
Dr. Gary Euler
Judy Gantt
Dr. Jacqueline Gindler
Susan Good
Dalye Guris
Penina Haber
Dr. Steve Hadler
Dr. Iain Hardy
Dr. Sandra Holmes
Dr. Sonja Hutchins
Dr. Alan Kendal
Dr. Charles LeBaron
Mark Miller
Dr. W. Orenstein
Susan Roof
Steve Rosenthal
Bob Snyder
Dr. Peter Strebel
Dr. Ray Strikas
Dr. Roland Sutter
Frederik VanLoon
Dr. Walter Williams
Dr. Jessie Wing
Dr. J. Watson
Dr. Melinda Wharton
Elizabeth Zell

ATTENDEES CONTINUED:

Department of Defense
Dr. Michael Peterson

Food and Drug Administration
B.F. Anthony
Julia Barrett
Dr. Karen Goldenthal
Phil Krause
Dr. Margaret Mitrane

Health Care Financing Adm stration
Cindy Ruff

Navy Environmental Health nter
Ben Mitchell

National Vaccine Injury Cor ensation Program
Leslie Ball

Others Present
Florence Berut, Connaught Laboratories Inc.
Karen Batoosinge, Pediatric News
Dr. Dee Breeden, S.C. Department of Health and Environmental Control
Maureen Caulfield, Wyeth-Ayerst
Jill Chamberlin, Vaccine Bulletin
Dr. Ruth Ann Dunn, Michigan Department of Public Health
Peter C. Fusco, North American Vaccine, Inc.
Jesse E. Greene, R.N., S.C. Department of Health and Environmental Cont
Dr. Jill Hackell, Lederle-Praxis Biologicals
A.J. Hostetter, AP
Barbara Howe, SmithKline Beecham
Clifton N. Irby, Christian Science Committee
Cheryl Pokalo Jones, Infectious Diseases in Children
Kathy Jordon, NAPNAP
Dr. David Krause, SmithKline, Beecham
Brian A. Lortie, SmithKline, Beecham
Carol McPhillips-Tangum, Prudential Center for Health Care Research
Francois Meurice, SmithKline Beecham
Dr. Carlton Meschievitz, Connaught Laboratories
Dr. David Nalin, MRL
Stan Plotkin, Pasteur-Merieux-Connaught
Leoff Porgos, Merck & Co.
Frederic E. Shaw, M.D., J.D., Health Policy Group
Robert G. Shannon, Merck & Co.
Judith Shindman, Connaught Laboratories, Ltd.
Dan Soland, Smith Kline Beecham
Barbara Sweeney, NAPNAP
Deborah A. Vaz, VRI
Thomas Vernon, Merck Vaccine Division
David West, Merck Laboratories
Dr. Jo White, Merck Research Laboratories
Tim Wissman, Merck & Co.

Summary of Agreed-Upon Actions

Staff of the National Immunization Program (NIP) will work with FDA to r lve the issue on inconsistency of the package inserts and ACIP recommendations. T s will be addressed at the February, 1995, ACIP meeting.

Comment on the varicella recommendation are due to Gloria Kovach by No nber 10.

November 15 is the due date for comments on the draft statement, "Prevent and Control of Serogroup C Meningococcal Disease: Evaluation and Manageme of Outbreaks."

A working group was formed to draft a new polio recommendation. The m bers are: Dr. B. DeBuono (Chair), Dr. J. Hackell (consultant), Dr. N. Hails, Dr. C. eschievitz (consultant), Dr. J. Ward, and Dr. R. Zimmerman.

A working group on adolescent immunization was formed. Members of the rking group are: Dr. N. Hails (Chair), Dr. A. Elster (consultant), Dr. J. Ward, a Dr. W. Williams. NIP staff will work with this group to develop a draft adolescent immunization statement for the February, 1995 ACIP meeting.

Dr. Steve Hadler and staff will draft some principles and guidelines on com ation products for the February, 1995, ACIP meeting. Manufacturers should sub t information to Dr. Hadler by November 20.

One-half day of the June, 1995, ACIP meeting will be dedicated to discussir acellular pertussis vaccines and efficacy trials of infants.

A working group to discuss WIC's immunization program was formed to fo ulate a draft recommendation. Members of this working group are: Dr. F. Guerr Chair), Dr. B. DeBuono, Dr. R. Jackson, Dr. E. Maes.

Comments are due to Gloria Kovach by December 1, on the draft recomme ation for hepatitis B.

NIP is to complete a draft statement on vaccine safety changes in ACIP recommendations following a review of the IOM report on vaccine safety.

Dr. Gina Rabinovich will mail the National Vaccine Program report to ACI nembers.

MINUTES

Dr. Jeffrey Davis, Chairman of the Advisory Committee on Immunization I ctices (ACIP), called the meeting to order at 8:35 a.m.

Dr. Dixie Snider, Acting Associate Director for Science for CDC and Acting xecutive Secretary for ACIP, welcomed Dr. Marie R. Griffin from Vanderbilt Unive ty Medical Center and Dr. Fernando Guerra from the San Antonio Metro Health Distr who have been appointed to the ACIP.

Dr. Snider also announced several changes in ex officio and liaison member Dr. Jerry Zelinger has joined the ACIP from the Health Care Financing Administrati (HCFA). Dr. Cindy Ruff represented Dr. Zelinger at this meeting. Dr. Stanley Gall m the University of Louisville School of Medicine has replaced Dr. Marvin Amste the liaison from the American College of Obstetricians and Gynecologists. Also ne National Vaccine Program (NVP) will be appointing a liaison to replace Dr. ny Robbins. Dr. Gina Rabinovich from the National Institutes of Health (NIH ill be presenting the NVP update at this meeting.

Finally, two new liaison organizations were welcomed to ACIP. The Associ n of Teachers of Preventive Medicine represented by Dr. Richard Clover of the iversity of Texas Medical Branch at Galveston, and the Pharmaceutical Research and Manufacturers of America, represented by Dr. Thomas L. Copmann, Biote ology and Biologics Regulatory and Scientific Affairs.

Dr. Davis then asked members to complete and return by Nov. 1 a handout lowing ACIP material to be transmitted electronically.

Dr. Davis also said that an agreed-upon meeting about the inconsistency of ckage inserts--committed to by Dr. Carolyn Hardegree, FDA-- had not as yet occu ed. It is scheduled for Nov. 21, and a report of this meeting will be provided at the t meeting of the ACIP.

The 75 people in attendance then introduced themselves, followed by introd ions and declarations of potential conflicts of interest by the appointed members.

Dr. Steve Schoenbaum has no consulting relationship with any pharmaceuti company. His wife has stock in Abbott Laboratories, Amgen Inc., Bristol Myers Squil Glaxo, and Merck Sharpe & Dohme (MSD).

Dr. Marie Griffin served as a consultant for Searle.

Dr. Joel Ward has no financial interest in any pharmaceutical company. T Research Institute at UCLA, which he directs, receives some funding from MSD and ithKline Beecham (SKB).

Dr. Rudolph Jackson has a potential conflict of interest with Wyeth.

Dr. Ed Thompson has served as a consultant for Connaught.

Dr. Nea Halsey has no financial interest in any of the vaccine manufacturer ıe has received grant support in the last 12 months from Pasteur-Merieux, Connau t Labs, and SKB. He has received travel support from SKB and has been promisec ıch support from the Consortium of European Manufacturers.

Dr. Kathy Edwards is currently receiving funding from Sclavo, Biocene and ederle-Praxis. She is doing some consulting for SKB and is on the speaker's burea 'or Connaught and Lederle.

Dr. Fernando Guerra is the principal investigator for a field trial using Am ĸ. He has also served as a consultant for the Salon Consulting Group and he has prev sly received a grant from MSD.

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

Minutes Approved

Dr. Davis asked members of the Committee if the minutes from the June, 1 ACIP meeting were accurate and complete. The minutes were accepted as distrib d.

Immunization Coverage in the United States

Ms. Elizabeth Zell summarized vaccination coverage for all children in the ited States, determined by the National Health Interview Survey. She noted tha 'or each vaccine, coverage increased from 1992 to 1993, but that differences in cover e levels have widened by poverty level and race (levels are lower for the poor and b ks, respectively). The coverage levels, by vaccine, range from 16% (for hepatit 3) to 88% (for DTP3); these levels are detailed in the Oct. 7, 1994, *MMWR*.

Varicella Vaccine Update

Dr. Sandra Holmes, National Immunization Program (NIP), updated the gr ɔ on CDC's varicella surveillance projects. Three sites --Philadelphia, Los Angeles County, and Travis County (Texas)--have been ignated as active surveillance sites. She called members' attention to the revision of th lraft recommendations for varicella prevention in three areas: health-care worke (pp. 20-

21), VZIG for pregnant women (pp. 37-38), and acyclovir (pp. 11-12). She quested that ACIP members return any comments by Nov. 10.

Next, Dr. Jo White of MSD updated the Committee on the status of VARIV ζ, Merck's varicella vaccine. The license has been applied for with FDA. She owed data on the vaccine's good antibody persistence in healthy children and adu 3 years after vaccination. Breakthrough rates are less than 1% a year. Two post-n keting surveillance studies are planned. One with Kaiser Northern, involving 20,0 30,000 children, to look for serious adverse effects. The other, a day care and fam effectiveness study, will follow up 1,000 children for 10 years. In response t ι request, Dr. White agreed to distribute a table of her data on antibody titers to the IP.

Vaccine Safety Update

Next, Dr. Robert Chen gave an overview of vaccine safety in general. Imm zations are definitely cost-effective, he said, and will be needed indefinitely unless a sease is eradicated. High vaccine coverage results in an increase in both causal and incidental vaccine adverse events: this monitoring is needed to maintain public confide . VAERS is now NIP's largest surveillance system, receiving about 10,000 rep s annually. These reports have received substantial media attention recently. 'hile VAERs is needed, it is limited in its scientific utility, he said. Most VAERS orts are of adverse events without unique laboratory or clinical findings attributable vaccine. Epidemiologic studies are needed in such settings to evaluate whether vaccin d persons are more likely to have such adverse events. VAERS reports provide less th one- quarter of the information needed for such an epidemiologic evaluation. Al natives such as the large-linked database are needed to provide more information r rding the relationship between vaccine and adverse events.

Next, Dr. John Glasser discussed how large-linked database studies show gr promise in epidemiologic studies. Since 1991, CDC has worked with four health mai nance organizations to create vaccination registries and link them with other medi records for a cohort of over 500,000 children 0-6 years of age. Taking advantage o iversity in timing of actual vaccinations administered, such linked database studies to l used to sort out the individual effects from the combined effects of some vaccinatio e.g., DTP + OPV and infection site abscesses).

Revision of ACIP Recommendations Based on Findings of the Institute of M icine (IOM) Report on Vaccine Safety

Dr. Phil Rhodes summarized and clarified three major conclusions from the iller study, "Pertussis Immunization and Serious Acute Neurologic Illnesses in Cl lren" (Br Med J 1993; 307:1171-6). Then Dr. Jessica Tuttle went over proposed upd of current ACIP recommendations in accordance with the IOM reports. Ther as some discussion about the distribution of risk within the 7-day period following D

vaccination. A working group was appointed to develop specific wording of change to the DTP recommendation to be voted on later.

Regarding the risks associated with MMR vaccine, the ACIP decided to del the phrase "clinically significant" in the phrase "Children with a previous histo of thrombocytopenic purpura or thrombocytopenia at the time of scheduled va nation may be at increased risk for *clinically significant* thrombocytopenia followin MMR".

Members were asked to mail in comments on the *MMWR* supplement, conta ed in the briefing book, and for advice on whether to reprint the IOM report in conj ction with the ACIP response to the IOM report in the *MMWR*. The sense of the Con ttee was that reprinting the IOM report would only detract from the ACIP recomme ation.

Update on Vaccine Schedule Simplification

Dr. Jacqueline Gindler updated the ACIP on progress made by the working oup to simplify the vaccine schedule. CDC is working with a contractor to develop nd field test several formats for a simplified schedule. The ACIP voted to call this s edule the "Recommended Childhood Immunization Schedule--United States, 1995," an to permit the Td booster to be given between 11 and 16 years of age. The schedule w be published by the AAP, AAFP, and by CDC in the *MMWR* in January 1995.

Dr. Gindler also reviewed issues related to accelerated immunization, discus l the minimum recommended intervals between vaccine doses, and presented a sa ble accelerated schedule. Dr. Halsey noted that there is potential confusion ass ated with the accelerated Hib vaccination schedule because one Hib product requires y a two dose primary series, and the other two products require a three dose prima series. Dr. Tom Vernon agreed to ask MSD officials whether it would be acceptab f the schedule simply recommends three (or two, depending on age) doses of any ensed Hib conjugate vaccine, recognizing that some children who receive the MSD pro ct will receive an extra dose.

Revision of the Meningococcal Vaccine Recommendation

Dr. Jay Wenger briefly outlined the revisions in the ACIP draft recommend on on "Prevention and Control of Serogroup C Meningococcal Disease: Evaluatio nd Management of Outbreaks". He asked for written comments to be returne to Gloria Kovach by Nov. 15.

Review of Draft Recommendation on BCG

Dr. Halsey said that the BCG Working Group was very near to completing final statement on BCG to be published jointly by the ACIP and the Advisory C ncil for Elimination of Tuberculosis (ACET), with consultation from the Hospital In ction

Control Practices Advisory Committee (HICPAC). Detailed comments from ost ACIP members have been incorporated. The document will be approved by ACE it their next meeting, in October 1994, so Dr. Halsey needed any proposed changes October 21. The final draft of the recommendation should be approved by the next CIP meeting.

Revision of the Polio Vaccination Recommendations

Dr. Roland Sutter reviewed the changes in the revised ACIP polio statemen ibsequent to the ACIP review of the first draft and discussed still-unresolved issues. I Carlton Meschievitz, Connaught Laboratories, presented the latest data on sequenti chedules.

One issue, the minimum timing between vaccine doses, was resolved by a vo of 9-1. ACIP members agreed to retain the proposed wording that the new minimu interval between doses for those who begin the series late is 4 weeks. A second issue whether to include a permissive recommendation to present a schedule for sequential II OPV vaccination to parents as an alternative to the schedule using OPV only, wa not resolved.

Suggestions for changes in the recommendation from members included me ning that the International Committee on Polio Eradication has concluded that there i o circulation of wild poliovirus in the Western Hemisphere; retitling the state nt (to "Maintaining a Polio-Free Status"; that is, drop the word "control"); and a ng a summary at the beginning of the statement.

Many members were concerned that, because polio eradication has been ach ved in the Americas, a sequential schedule should now be more seriously considered to duce the risk of vaccine-associated paralytic poliomyelitis. A working group was for d to address this issue and to identify the information needs and subissues that w ld be considered critical for the ACIP to consider making a change to recommend ; a sequential schedule. This group is composed of Drs. Halsey, Ward, Zimme an, and DeBuono with Drs. Meschievitz (Connaught) and Jill Hackell (Lederle) as c ultants. The ACIP did vote unanimously, by straw vote, to state that it continues to dorse that all children should receive OPV.

Also, it was noted that CDC staff are considering whether the IOM should asked to convene an expert group to address the need for a sequential IPV-OPV sche le: twice in the past (1977 and 1988) the IOM has addressed this issue.

Status of Development of New Combination Vaccines (Manufacturers' Repo)

Dr. Steve Hadler, NIP, said that manufacturers have frequently expressed t desire to have early input from advisory committees about how combination vaccines ight be used. Therefore, attendees from Lederle, SKB, Connaught and Merck wer nvited to

update the ACIP on their combination vaccines and pose critical issues whic night benefit from ACIP input.

Dr. Hackell from Lederle summarized the general problems with developme of combination vaccines. She said that new standard product quality control a release tests for combination products need to be developed and that we need to be reful that vaccine potency is not sacrificed for the convenience of administration. She ted the potential new vaccines and the following future possible combination vaccin a pediatric meningitis vaccine (with glycoconjugates against *Hemophilus influe* ue *b* (Hib), *Streptococcus pneumoniae*, and *Meningococcus*); a STD vaccine (with V, herpes, hepatitis B); a viral pneumonia vaccine and an otitis media vaccine She emphasized that both policymakers and manufacturers need to work togeth o keep vaccine schedules simple and to combine vaccines in sensible ways to minimi confusion.

Dr. B. Howe from SKB gave a status report on SKB's seven combination p ucts. Results of two studies with its DTP (whole-cell)-hepatitis B combination vac e outside the United States revealed that this vaccine has had 100% or close to 100% cine response rates. In the U.S. pediatric vaccine program, SKB has the followi products for development of combinations: DTPw (available through the Michigan I artment of Health), PRP-T, Engerix-B, and DTPa (acellular). A recent preliminary dy in Germany of the last product demonstrated vaccine efficacy of 89.9%. The (nbined pediatric vaccines under development in the United States are:

DTPw-Hib
DTPw-HB-Hib
DTPa
DTPa-HB-Hib
DTPa-eIPV-HB-Hib

Dr. Meschievitz, Connaught, said that Connaught/Pasteur Merieux is curre y working on the following vaccines: DTP/PRP-T; DTaP/PRP-T, and DTP-IPV. Conn ght Laboratories/Pasteur-Merieu manufacturer is also considering at the followi vaccines:

Meningococcal conjugates (serotypes A,C,Y, and W-135)
Lyme disease
Rabies (Vero cell)
AIK-C measles
Pertussis acellular
Typhoid polysaccharide

Connaught is also considering at vaccine vectors for rabies, Japanese encepl itis, malaria, and HIV.

Dr. David West presented data from Merck. It has three combination proc ts under development:

MMR varicella
hepatitis A/hepatitis B
*H. influenza*e type b/hepatitis B

A phase III clinical trial is planned for the MMR varicella combination pro :t next year. The hepatitis A/hepatitis B vaccine is achieving 97% seroconversion r s following the third dose, and phase III trials in adolescents and adults are a cipated. COMVAX (the Hib-HB vaccine) has been assessed in several clinical trials, which the antibody response has been high (99%).

Dr. West then outlined several issues which he felt would benefit from ACI consideration:

1. New combination vaccines should not increase adverse effects · decrease the immune potency of any antigen to a clinically significant c ree.
2. Standards are needed (for example, definition of clinically im tant end points, sample sizes, power) on which to base studies of vacci interactions and mixed vaccine regimens involving vaccines fr different manufacturers.
3. Logistical simplicity vs. over immunization, when using combi ion vaccines (e.g., DTP-Hib-HB vaccine)

During follow-up discussion, ACIP members concurred that they might nee o consider developing guiding principles for such issues and suggested that manufactu submit issues by November 19 to Dr. Hadler so this effort could begin. A member the audience noted that FDA has a book in press that summarizes a workshop combination vaccines convened by FDA in August 1993.

Dr. Rabinovich, NIH, said that perhaps the most useful contribution from ACIP would be the development of a policy statement addressing the issues and p meters that the ACIP would consider for the introduction of new combination vacc s. This statement could include what characteristics of new vaccines would be most eful for universal use. Another audience member said ACIP should look into Euro n and U.S. older formulations of vaccines with an eye toward developing a "globa andard."

Update on the Status of the Vaccines for Children Program (VFC)

Dr. Jose Cordero, Deputy Director of the NIP, said that to assure sustainal networks for immunizing all of the 4 million children born every year, the infrastruc e of immunization delivery services must be enhanced and partnerships with pri e providers must be expanded. Ten regional meetings focused on reaching a developing

such partnerships have just been completed. As of October 1, one half of t states were ready to provide vaccines to private providers through VFC. The con ıter programs needed to order vaccine were operating on September 6 and orde began to be received. States that have ordered vaccine through VFC have received t r vaccines, and vaccination with VFC supplied vaccines is beginning.

Dr. Cordero also updated the ACIP on the Government Accounting Office AO) report, an audit of the VFC conducted this summer. That report noted tha nly 4 of 15 contracts had been awarded in July; however, all 15 have now been awa ed. The report also charged CDC with not doing enough to enroll. CDC had always tended this to be the states' job, Dr. Cordero said, and states are enrolling physici to participate in the VFC program The report also stated that CDC had base administrative fee caps on costs submitted by providers. HCFA sets fee cap he noted, and when the data needed were not available, HCFA relied on AAP data. FA is undertaking a study to determine true costs and to set future fee caps. The AO also charged that the VFC did not have an adequate system of accountability; h ever, Dr. Cordero said that financial accountability is an essential part of the VFC pı ram. The GAO also raised the issue of evaluation of the VFC. Such a plan has been veloped.

The meeting adjourned for the day at 6:00 p.m. The ACIP reconvened its' eeting on October 20 at 8:30 a.m.

Adolescent and Adult Immunization

Dr. Halsey introduced this topic by reviewing the rationale for having a rou ıe early adolescent visit. He outlined a series of recommendations for the ACIP to sider during this meeting:

1. Recommend an early adolescent immunization visit.
2. Recommend Td booster at 11-12 (or 14-16) years.
3. Recommend catch-up MMR2 at 11-12 years.
4. Recommend hepatitis B vaccination catch-up during adolescer

Dr. Art Elster from the AMA provided rationale regarding how an adolesc visit would fit into a larger strategy to deliver care to adolescents. He said an e adolescent visit could be a time to assess 14 topics/health conditions ranging om injury prevention and preventing eating disorders to prevention of infectious disea . Dr. Roland Sutter provided data from the United States and other countries on e prevalence of antibodies to tetanus as a consideration for lowering the age he Td booster dose to 11-12 years. He concluded that tetanus immunity levels are wer in school-aged adolescents than expected.

The ACIP then voted on a motion to recommend a routine immunization vi at 11-12 years of age. This motion passed unanimous among the eight members pre t (Drs. Schoenbaum and Thompson were absent.)

The ACIP then voted on a motion to recommend a routine booster dose of ' at 11-16 years of age. This motion also passed unanimously, 8-0.

Finally, the ACIP voted on a motion that "during this early immunization v , all children 11-12 years of age who have not previously received two doses of M R after 12 months of age should receive another second dose of MMR at that time." NIP staff will develop the correct wording of this statement. The motion passed unan ously, 8-0.

Dr. Hal Margolis led a discussion of hepatitis B adolescent immunization. hough adolescent hepatitis B immunization is not cost-saving, per se, he said the c per year of life saved ($5,500-$7,917) are within the range considered acceptable for ier preventive interventions, such as isoniazid preventive therapy. A motion th all individuals not previously vaccinated with hepatitis B vaccine be vaccinated 11-12 years of age passed unanimously, 8-0.

Revised Recommendations for Hepatitis B Vaccination

Dr. Margolis presented adult hepatitis B issues unresolved from the last AC meeting. He reviewed how the hepatitis B working group had resolved multiple issue cluding post-vaccination testing (see his handout, entitled "Summary of discussions ACIP working group on adult immunizations," dated Oct. 18, 1994.) It was deci that all ACIP members needed additional time to review that handout and return t comments by December 1; a fully revised draft statement will be sent to me ers well before the next meeting.

The Need for ACIP Recommendations on Immunization Practices: Immuni ion Linkage with WIC

Dr. Hadler said the ACIP was being asked to comment on the need to deve recommendations/guidelines to enhance childhood immunization programs, becoming involved with recommendations regarding immunization practices. He intr ced Dr. Ed Maes, NIP, who led a discussion of collaborative studies with WIC, the Supplemental Food Program for Women, Infants, and Children which pro s support to 40% of the U.S. annual birth cohort (4.4 million low-income children). Maes asked the committee to consider the following questions:

1. Does the ACIP believe it has a role in developing recommenda ns regarding programmatic operations which might increase vac tion coverage levels?

2. If so, how would the Committee like to proceed in making pr ammatic recommendations?
3. Does the ACIP find the data compelling to recommend the lin ge of immunization with WIC?

Drs. Charles Lebaron and Sonja Hutchins, NIP, then reviewed studies conc ted in New York City and Chicago, respectively, which demonstrated the effective s of linking WIC and immunization services on increasing immunization coverag Mr. Stan Garnett, the Director of WIC at the federal level, said he thought WIC was perfect match for the Immunization Program, but said the infrastructure would be ked by the addition of 1 million participants during the next 2 years. He said that Con ss recently allocated $10 million for immunization through WIC programs.

During follow-up discussion, ACIP members indicated they were impressed th the increases in coverage associated with the interventions and agreed to review statement encouraging linkages between WIC and immunization in a future meeting. working group of ACIP members and CDC staff will be formed.

Adult Immunizations (continued)

Dr. Pierce Gardner read the following statement which he hoped the ACIP uld adopt:

> The ACIP strongly recommends that age 50 years be established as a ecific time to review overall immunization status, to give tetanus-diphtheri immunization(s) as indicated, and to determine specifically whether t patient has a risk factor that indicates the need to receive a dose of pneumoc cal vaccine and begin annual influenza immunization.

The American College of Physicians is recommending this statement. The A IP voted unanimously to endorse this statement (with certain modifications suggested committee members). How this approved proposal will be made public will resolved by Dr. Gardner and NIP staff.

Next, Dr. Walter Williams, NIP, updated the ACIP on major programmati sues related to adult immunization. One was the National Vaccine Advisory Co ittee Report on Adult Immunization, which was adopted in January and summa d in the October 12 issue of *JAMA*. It establishes five major adult immunization go for the United States and makes 18 recommendations to achieve them. The recom dations state that the CDC should assume a more prominent role in adult immuniz n and a federal adult immunization grant program should be established to assist st and local health departments.

Second, publication of a GAO report on adult pneumococcal and influenza ccination under Medicare is imminent. The findings of this report will hopefully ide y areas inwhich HHS efforts can be improved.

Third, vaccination levels have improved to protect against influenza and pn nococcal disease. Fourth, HCFA has launched a major public relations campaign to prove immunization coverage rates against these two diseases. Dr. Williams also r iewed NCHS provisional mortality data for these diseases and announced that Adı Immunization Awareness Week will be October 23-29, 1994.

CDC will be working with other HHS agencies in a major effort to develop trategic implementation plan for the NVAC recommendations. CDC will also work ore closely with HCFA to improve use of the covered benefits under Medicare.

NCES Annex Material (continued)

The ACIP voted unanimously to adopt the wording of an ACIP working gr on the NCES data regarding DTP. (See handout #1.)

Recommendations for Prevention of Hepatitis A: Hepatitis A Vaccine and I une Globulin

Dr. Craig Shapiro, NCID, reviewed the epidemiology of hepatitis A and cu nt and proposed ACIP recommendations for preventing it. He said that SKB has lied for licensure of a hepatitis A vaccine. A draft of the recommendations has bee eviewed by the hepatitis A working group, and Dr. Shapiro is incorporating suggest s. Dr. Shapiro will distribute a new draft to the full committee and asked for com nts from committee and liaison members so the draft can be reworked before the ne neeting.

Vaccination of Health Care Workers (HCWs)

Dr. Ray Strikas, NIP, updated the ACIP on the recent publication of a spe supplement to vol. 10 of the *American Journal of Preventive Medicine*, entitl "Immunization in Medical Education." The supplement was published coo atively by CDC and the Association of Teachers of Preventive Medicine as part of a p ect to develop immunization materials for medical students, residents, and practic physicians. Questions or comments should be addressed to Dr. Strikas. Si ar documents on nursing and public health education will hopefully be develo .

Dr. Strikas then updated the Committee on the status of a draft statement vaccination recommendations for HCWs, being jointly issued by ACIP and CPAC. He felt staff could not further proceed with the document until told how to solve handling of varicella vaccine, BCG, and hepatitis B recommendations. The mmittee favored resolving the BCG and hepatitis B issues and then advance the dra vith a

Dr. Leslie Ball updated the ACIP on this program, which has met the basic ılicy goals it established 6 years ago. The Vaccine Injury Table revision should be pul hed shortly. The process of adding Hib and hepatitis B vaccines is currently un rway; this requires both legislation and the rulemaking process.

Public Comment

Dr. Davis asked if there was any public comment. There was none. He re ıded members that the dates of the next ACIP meeting are February 9-10, 1995. e said that an adolescent immunization working group will be appointed later. T meeting was adjourned at 3:00 p.m.

I hereby certify that, to the best of my knowledge, the 'egoing summary of minutes is accurate and complete.

Jeffrey P. Davis, MD, Chairperson

Date: 2/28/95

ATTACHMENT I

The National Childhood Encephalopathy Study (NCES) and other controlled epide ɔlogical studies have provided evidence that DTP can cause acute encephalopathy (ref A rslade, 1981; Walker, 1988; Gale, 1990; Griffin, 1990; IOM, 1991). This adverse eve occurs rarely with an estimated risk of betwen 0.0 and 10.5 per million DTP immunizatic (IOM, 1991).

New data from a follow-up of the NCES indicate that children who experienced erious, acute neurologic illness were significantly more likely 10 years later to have chroni ervous system dysfunction than control children. These children with chronic nervoı ɜystem dysfunction were more likely than controls to have received DTP within 7 days o ɹset of their original serious acute neurological illness [12/367 (3.3%) vs. 6/723 (0.8%)] Miller, 1993).

After reviewing the follow-up data, the IOM concluded that the NCES provided idence of an association between DTP and chronic nervous system dysfunction in children ɹo had developed a serious acute neurologic illness following DTP. The committee pr ɔsed 3 possible explanations for this association: 1) the acute neurologic illness and su quent chronic nervous system dysfunction might have been caused by DTP; 2) DTP migh rigger an acute neurologic illness and subsequent chronic nervous system dysfunct that otherwise would not have occurred in children with underlying brain or n ɹbolic

abnormalities; or 3) DTP might cause an acute neurologic illness in ch ren with underlying brain or metabolic abnormalities that could have led to chronic ner is system dysfunction even if the acute neurologic illness had not developed (ref IOM). The IOM concluded that the NCES data do not support one explanation over another.

According to the IOM, the balance of evidence was consistent with a causal i itionship between DTP and some forms of chronic nervous system disorders in ch ren who developed an acute neurological disorder following DTP. However, the IOM als included that the data are insufficient to indicate whether or not DTP increases the ove l risk in children of chronic nervous system dysfunction.

A subcommittee of the National Vaccine Advisory Committee also reviewed the idy, and concluded that the data are insufficient to accept or reject whether DTP adn istration prior to the acute, neurologic event influenced the potential for neurologic dys ction 10 years later (Ad hoc Subcommittee of the NVAC, 1994).

The ACIP concurs with this evaluation.

Although the NCES examined and reported risk in the 7 days following DTI he data indicate that the increased risk of serious acute neurologic illness occurs prim y in the first 3 days after DTP (Alderslade, 1981). Thus, if an association between DTP a chronic encephalopathy exists, the risk is primarily in the first 3 days following DTP.