DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION

MINUTES OF MEETING

Advisory Committee on Immunization Practices
February 9-10, 1993
Atlanta, Georgia

ADVISORY COMMITTEE ON IMMUNIZATION PRACT ES
Centers for Disease Control and Prevention
Auditorium A
February 9-10, 1993

FEBRUARY 9

1:00 PM	General Recommendations on Immunization	Dr. . Watson
2:00 PM	Update on Immunization Levels of Pre-School Children	Dr. . Zell
2:30 PM	Pre-Licensure Studies of Hib Conjugate-DTP Combinations	Dr. . Fritzell C naught Dr. . Haeckel L erle
3:15 PM	BREAK	
3:45 PM	Draft Statement on Hib Vaccine	Dr. . Zangwill
4:00 PM	Draft ACIP Statement on DTP-HbOC	Dr . Sutter Dr . Wenger
4:20 PM	Follow-up on MSD Hib Conjugate	Dr . Wenger
4:30 PM	Safety of Simultaneous Vaccination: Analysis of VAERS Data	Dr . Chen
5:00 PM	Simplification of Immunization	Dr . Halsey

FEBRUARY 10

8:00 AM	Influenza Global and U.S. Surveillance Virus Characterization and Influenza Vaccine Strain Selection Revision of Influenza Vaccine Recommendations Revision of Influenza Antiviral Recommendations GBS and 1990-91 Influenza Vaccination	Dr . Arden Dr . Chen Dr . Cox Dr . Simonsen
9:30 AM	Group C Meningococcal Meningitis Clusters -- Indications for School/Community Immunization Campaigns	Dr . Jackson
10:00 AM	BREAK	

ADVISORY COMMITTEE ON IMMUNIZATION PRAC' CES
Centers for Disease Control and Prevention
Auditorium A
February 9-10, 1993

FEBRUARY 10 (Continued)

10:30 AM	Injury Compensation Update	M T. Balbier, Jr. N CP
11:00 AM	Update on the National Vaccine Program	D K. Bart N
11:15 AM	Polio in the Netherlands	D F. VanLoon
11:30 AM	Update on BCG Meta-analyses	D L. Geiter
11:45 AM	LUNCH	
12:45 PM	Potential Future Adult Immunization Issues	D P. Gardner D Wm. Schaffner
1:15 PM	Immunization for Health Care Workers: Review of ACIP Recommendations	D M. Alter D C. Shapiro D R. Strikas
2:00 PM	General Recommendations on Immunization	D J. Watson
2:30 PM	Immunization of Bone Marrow Transplant	D M. Grabowsky
2:45 PM	Public Comment	
3:00 PM	ADJOURN	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION

MINUTES OF MEETING

Advisory Committee on Immunization Practices
February 9 & 10, 1993
Atlanta, Georgia

COMMITTEE MEMBERS PRESENT

Dr. Samuel L. Katz, Chairman
Dr. Mary Lou Clements
Dr. Barbara Ann DeBuono
Dr. Kathryn Edwards
Dr. Neal Halsey
Dr. Gregory Istre
Dr. Rudolph Jackson
Dr. Carlos Ramirez-Ronda
Dr. Fred Thompson
Dr. Joel Ward

Ex Officio Members

Dr. Carolyn Hardegree (FDA)

Liaison Representatives

Dr. Marvin Amstey (ACOG)
Dr. Pierce Gardner (ACP)
Dr. Caroline B. Hall (AAP)
Dr. Edward Mortimer, Jr. (AMA)
Dr. Georges Peter (AAP)
Dr. Michael Peterson (DOD)
Dr. William Schaffner, II (AHA)
Dr. Susan E. Tamblyn (NACI)
Dr. Ronald C. Van Buren (AAFP)

Acting Executive Secretary

Dr. Stephen Hadler

NAVY ENVIRONMENTAL HEALTH CENTER

Capt. S. William Berg
Capt. Gil Potter

HHS STAFF PRESENT

NATIONAL INSTITUTES HEALTH

Dr. Regina Rabinovic NIAIP

CENTERS FOR DISEASE)NTROL

Office of the Direct :

Kevin Malone

National Center for ıfectious Diseases

Dr. Miriam Alter
Mary Broom
Dr. Louisa Chapman
Dr. Nancy Cox
Dr. Carmen Deseda
Rafael Harpez
Dr. Kenneth Herrman
Eric Mast
Dr. Joseph McDade
Helen Regnery
Dr. Craig Shapiro

National Center for :evention Services

Kenneth Anderson
Dr. Stephen L. Cochi
Dr. Bob Chen
Dr. Vance Dietz
Dr. Eugene Dini
Gary Euler
Conrad Ferrara
Judy Gantt
Dr. Larry Geiter
Jacqueline Gindler
Carrie Hartshorne

National Center for Prevention
Services Continued

Sonja Hutchinson
Gail King
Charles LeBard
Ed Maes
James Mize
Seleda M. Perryman
Dr. Dixie Snider
Dr. Raymond Strikas
Dr. Roland Sutter
Dr. Frederik Van Loon
Dr. John Watson
Dr. Melinda Wharton
Dr. Elizabeth Zell

OTHERS PRESENT

Shelby B. Abernathy, DeKalb County Board of Health
Stefan Antonsson, Forest Laboratories
Thom Balbier, HRSA, DVIC
Dr. Julia Barrett, FDA
Karen Campbell, NAPNAP
Jill W. Chamberlain, Vaccine Bulletin
Kathleen Crozier, Infectious Diseases in Children
E. Esler, FDA/CBER
Catharine Eten, Wyeth-Ayerst
Donna Freeman, FDA/CBER
Bernard Fritzell, Connaught Laboratories, Inc.
Dr. Ian Furminger, Medeva International
Dr. Carol Frankel, Medeva International
Carl Frasch, FDA
Dr. Karen L. Goldenthal, FDA
Jill Hackell, Lederle-Praxis Biologicals
Dr. Gary Horwith, Wyeth-Amerst
Cynthia Howe, Institute of Medicine
Barbara Howe, SmithKline Beecham
Robert Kohberger, Lederle-Praxis Biologicals
Edward B. Levin, North American Vaccine, Inc.
Wenlii Lin, NAVA
Kevin G. Lokay, Merck Vaccine
Carol Marcus-Sekura, FDA/CBER
Charles S. Marwick, JAMA
Sharon Mates, North American Vaccine
Frank Malinoski, Lederle-Praxis Biologicals
Carlton Meschievitz, Connaught Labs
Mike Paradiso, Lederle-Praxis Biologicals
Sharon Phillips, Parke-Davis Co.
Dr. Stanley A. Plotkin, Pasteur-Merieux-Gonnaught
Dr. Gregory A. Poland, Mayo Clinic
Lorraine Radick, Lederle-Praxis Biologicals
Dr. Stuart L. Scheiner, Forest Labs

Claudia Schmidt, Sero-Merieux
Robert L. Scott, Lederle Laboratories
Laura Searcy, National Organization of Pediatric Nurse sociates
and Practitioners
Judith Shindman, Connaught Laboratories Ltd.
Dan Soland, Connaught Labs
Kathleen Stratton, Institute of Medicine
Matt Strasburger, Merck Vaccine Division
Dr. Linda G. Teague, FDA
Tito Ubertini, North American Vaccine
George Welu, Connaught Laboratories, Inc.
Jo White, Merck Research Laboratories
Dr. Jalal Zuberi, Morehouse School of Medicine

Executive Summary

On February 9-10, 1993, the Advisory Committee on Immunization Practices (A ?) convened at the Centers for Disease Control and Prevention (CDC) to discuss th status of numerous vaccine-preventable diseases and vaccine-related issues. Dr. Samuel tz, Chairperson, opened the meeting at 1:00 p.m. on February 9. Dr. Walter Orenste the new Acting Executive Secretary, was out of town; Dr. Stephen Hadler acted in his st l.

All ACIP and liaison members introduced themselves. The approximately 50 p ple in attendance also introduced themselves. They included reporters; vaccine manu turers; FDA, CDC, and Navy personnel; and members of interested health organizatior Dr. Hadler welcomed Dr. Barbara DeBuono, Director of the Rhode Island Departme of Health, as a new member. Several members then declared potential conflicts of interest

General Recommendations on Immunization

Dr. Jay Watson, ID, NCPS, reviewed the major changes that had been made in t draft ACIP statement on general recommendations on immunization. Then ACIP me bers discussed and voted on issues still outstanding.

Update on Immunization Levels of Pre-School Children

Ms. Elizabeth E. Zell, ID, NCPS, updated the ACIP on the immunization levels 2-year-olds in 1991. Vaccination levels in this age-group have remained relatively constant ce 1985, except for measles, for which vaccination levels have increased to about 80% in 91. However, only 37%-56% of these children were fully vaccinated with 4 DTP, 3 io, and 1 measles-containing vaccines. Over 90% of 3- to 11-month-old children had rece d at least one vaccination.

Pre-Licensure Studies of Hib Conjugate-DTP Combinations

Dr. B. Fritzell from Connaught summarized safety and efficacy data on PRP-T, n presented data on the combination of PRP-T reconstituted with DTP vaccine.. I said that three controlled studies have shown that PRP-T/DTP is safe (reactogenicity is s ilar to that of DTP and PRP-T given separately) and immunogenic (85%-96% have a PRP a body titer ≥1 µg/mL).

Dr. J. Haeckel from Lederle summarized safety and efficacy data on Lederle's c bined DTP-Haemophilus combination vaccine. She said that large-scale studies show that safety in infants in a three-dose primary series is excellent. The immunogenicity of the v cine is equal to if not better than the separate administration of DTP and HbOC.

Draft Statement on Hib Vaccine

Dr. Kenneth Zangwill, BD, NCID, said that since FDA will probably soon licens one of the above vaccines, a new ACIP statement for use of these vaccines will be develop . He said that *MMWR* announcements about new vaccines have been drafted. He reques l guidance

about the issue of carrier priming. Dr. Zangwill requested members to review a ocument on this subject and send comments back to Gloria Kovach by March 19.

Draft ACIP Statement on DTP-HbOC

Dr. Roland Sutter, ID, NCPS, said CDC would also like to have an ACIP statem : available on DTP-HbOC as soon as it is released and briefly went through a draft statem . Members were asked to return comments to CDC by March 19.

Follow-up on MSD Hib Conjugate

Dr. Jay Wenger, DBMD, NCID, updated the ACIP on Merck lots of Hib conjuga vaccine that produced less-than-optimal seroconversion rates. Merck has distributed 12)0 doses of new vaccine, much less than the 350,000 they thought they'd need; phone respo :s to their announcement of suboptimal lots have also been much less than expected. No ditional cases of Hib associated with the questionable lots of vaccine have been reported

Safety of Simultaneous Vaccination: Analysis of VAERS Data

Dr. Robert Chen, ID, NCPS, said there has been some concern about safety of si ıltaneous administration of Hib and DTP vaccines in infants. Dr. Gail King, ID, NCPS, re :wed prelicensure data that demonstrated that giving Hib conjugate vaccines togethe ith other infant vaccines is a safe practice. However, CDC will continue to monitor safet ı actual use in larger numbers of children.

Mr. John Mullen, ID, NCPS, presented a preliminary analysis on safety of simul ıeous administration of DTP and Hib. There has been no increase in reported rates o hospitalization and death following administration of DTP with Hib, compared th rates reported after DTP alone. Additional analyses are under way.

Dr. Chen then discussed future analyses and directions in VAERS.

Hepatitis B Vaccination Programs

Mr. James Mize, ID, NCPS, discussed the implementation of the hepatitis B vac e program in various states.

Diphtheria--Russia

Dr. Melinda Wharton, ID, NCPS, summarized the current diphtheria epidemic i ıe Russian Federation, where an estimated 4,000 such cases occurred in 1992. CDC will col orate on a study to characterize circulating strains, and a vaccine efficacy study has been ir ıted.

The meeting closed for the day at 6:00 p.m. It began on February 10 at 8:00 a.m

Influenza

Dr. Nancy Cox, VR, NCID, discussed international influenza activity and the an ınic characteristics of recent influenza viruses that set the context for the influenza v ine strain recommendations made by the FDA Vaccine Advisory Panel on January 26. Th recommendation for the B component for the influenza vaccine for the 1993-34 s ıon is B/Panama/45/90. The final recommendations for the A(H3N2) and A(H1Nl) c ponents are being deferred until additional data are available and WHO makes its annu accine recommendations during the week of February 15. Dr. L. Simonsen followed w a brief summary of U.S. surveillance data. Dr. Nancy Arden then reviewed suggested isions for the influenza vaccine recommendations. Dr. Chen then described the final anal on the possible association of GBS and flu vaccine during the 1990-91 season. It was s ın that, for the high-risk population of persons 18-64 years of age, the benefit clearly outwe ed any potential risk; for the low-risk population in this age-group, there was a balance isk-benefit ratio. Discussion ended in the assignment of an ad hoc committee, composed o r. Clements, Dr. Halsey, Dr. Mortimer, and Dr. Chen, to come up with acceptable rding on GBS for the ACIP flu statement.

Group C Meningococcal Meningitis Clusters

Dr. Lisa Jackson briefly updated the group on the recent Canadian experience w increased cases of this disease, and discussed the occurrence and management of outbreak f this disease in the United States. The last ACIP statement on the vaccine for this di se was in 1985. She raised some questions about that statement. Dr. Katz said the Comm e was not prepared to revisit this statement now, but asked that the subject be added to a ure agenda.

Injury Compensation Update

Mr. T. Balbier, Jr., from the National Vaccine Injury Compensation Program, sai hat a review of that program had just been completed and submitted to Congress. It ıs very favorable regarding operations and management, but noted that resources are i fficient. He said that the Secretary of the Treasury has authority to terminate the vaccin cise tax, as of January 1, 1993, and that he has done so; thus, no additional funds are goi into the compensation trust fund.

After his presentation, Dr. Katz read a statement from Dr. Ken Bart, who was u ole to attend, about the new Administration's proposals regarding immunization. A p lic hearing is scheduled for February 24. Dr. Katz, who will speak at it on behalf of the A , asked for

direction from the Committee on what to say. Topics brought up were adult vac ıes, the need for flexibility in the system, and the importance of a registry and tracking s :em.

Polio in the Netherlands

Dr. Frederik Van Loon, ID, NCPS, summarized the recent polio outbreak in the I :herlands. A total of 67 cases (all but one in a religious, unvaccinated group) have been rep ed. The outbreak, which does not appear to have spread to the general population or to er countries, has apparently slowed down dramatically.

Update on the BCG Meta-analyses

Dr. Lawrence Geiter, TB, NCPS, briefly reviewed the BCG meta-analysis project, ıich was awarded to the Harvard School of Public Health in September.

Potential Future Adult Immunization Issues

Dr. Pierce Gardner said that if the currently recommended vaccines for adults w fully used, 35,000 deaths would be prevented each year. He said that the consensus c xperts he has consulted is that the recommended age of immunization for pneumococcal v :ine should be reduced; if it were given at 55 years or age instead of 65, the immune ;ponse and duration of that response would be longer. Secondly, he urged that a cost-b efit analysis be undertaken to see if a single, mid-life tetanus-diphtheria toxoid boos would be better than the currently recommended every 10-year booster. Third, he said tha he Amantadine recommendations are too broad and are ignored by practicing phys ıns. Finally, some are wondering if post-immunization serologic testing should be ro ne, at least for certain target groups.

Dr. Katz asked that the next agenda have a section on adult immunization, with representatives on prisons and colleges. He also asked Dr. Gardner to pull toge r data from the pending Task Force on Adult Immunization Green Book Committee m ing and present it at the June ACIP meeting.

Dr. William Schaffner urged that the ACIP recommendations be simpler and cle r. He also said that ACIP recommendations needed to be marketed as a product, not simp ɔublished in the *MMWR*.

Immunization for HCWs: Review of ACIP Recommendations

Drs. Ray Strikas, ID, NCPS, Miriam Alter, VR, NCID, and Craig Shapiro, VR, N ɔ, discussed immunization recommendations for HCWs and a revision of the BCG ction. Dr. Alter discussed the issue of post-vaccination testing for hepatitis B surface antib /. Dr. Shapiro discussed hepatitis A immunoprophylaxis for HCWs. Dr. Strikas then l a discussion centered around several questions in this ACIP statement.

Report of Ad Hoc Committee on Statement Regarding GBS within Influenza **ıtement**

Dr. Clements then presented a revised statement on the risk of GBS following in enza vaccine, which the Committee voted to include in the ACIP flu statement.

General Recommendations on Immunization

Dr. Jay Watson went over suggested changes to this ACIP Statement and the gr › voted on several issues.

Immunization of Bone Marrow Transplant Patients

Dr. Hadler said that progress on an ACIP statement on this subject has stalled a asked for direction. Dr. Katz said not to go forward with the statement for the time being ıd that he would take the responsibility for finding a group to liaison with on the statemer

Before closing, Dr. Katz asked for public comment. There was none. Members n requested that the June 2-3 ACIP meeting begin at 1:00 p.m. instead of in the m ing. Ms. Kovach will see if this can be arranged. The meeting adjourned at 3:40 p.m.

On February 9-10, 1993, the Advisory Committee on Immunization Practices (AC ') convened at the Centers for Disease Control and Prevention (CDC) to discuss th tatus of numerous vaccine-preventable diseases and vaccine-related issues. Dr. Samuel l z presided as Chairperson.

Dr. Katz opened the meeting at l:00 p.m., February 9, by announcing that Dr. Cl e Broome would no longer be Executive Secretary of ACIP because she had been named A ng Director of the Center for Prevention and Injury Control. Dr. Walter Orenstein : he new Acting Executive Secretary, but since he was in Washington advising the new A inistration on the initiative to purchase all childhood vaccines nationally, Dr. Stephen Hadl was acting in his stead.

All ACIP and liaison members introduced themselves. Dr. Katz then asked the approximately 50 people in attendance to introduce themselves. They included porters; vaccine manufacturers; FDA, CDC, and Navy personnel; and members of intere d health organizations.

Dr. Hadler welcomed Dr. Barbara DeBuono, Director of the Rhode Island Depa ent of Health, as a new member. Then he announced that there was a new conflict of erest form, Form FS450, that must be filled out by ACIP members and returned to Kitty Ar trong by March 1, 1993. Questions should be addressed to Ms. Gloria Kovach.

Dr. Hadler asked members to declare any potential conflicts of interest. Dr. Tec fortimer said he was a consultant to Lederle Laboratories. Dr. Katherine Edwards said s was conducting studies with vaccines from Lederle, Merck, Connaught, Evans, Meri c. Dr. Neal Halsey is currently conducting studies with funding from Connaught, Merck, a Pasteur-Merieux. Dr. Katz is beginning studies with vaccines from Biocine and Microge sys. Dr. Mary Lou Clements is doing HIV vaccine studies with Biocene, Genetech, Imm ogen, Pasteur-Merieux, and Bristol Myers. Dr. Georges Peter is participating in a Me vaccine study. Members with conflicts of interest about a particular vaccine were askec refrain from voting on that particular vaccine.

General Recommendations on Immunization

Dr. Jay Watson, ID, NCPS, reviewed the major changes that had been made in draft ACIP statement on general recommendations on immunization (Handouts #1 a #2). Then Committee members discussed and voted on issues still outstanding. Those re ved this morning were as follows:

1. Is new Table 8 acceptable? Yes, but add a qualifier regarding the va bility of antibody titers in products.
   Also, should the table state that HIV-infected patients on routine IGIV t apy should receive MMR vaccine? No, with caveat that much of information on Ta 8 is calculated, not based on studies with each individual product.
2. Relatedly, when should IG measles prophylaxis be given to measles- posed patients receiving high-dose IG therapy? Dr. Halsey offered to write up me general guidelines.

3. Do aerosolized steroids cause sufficient immunosuppression to cause reactions to live-virus vaccines? The ACIP voted that immunization sho delayed and that data are insufficient to suggest that such steroids are a contraindication.

4. What is the recommended distance between two vaccines given in th Committee consensus was to recommend to 1"-2"to minimize risk of ove reactions.

5. Does oral live typhoid (Ty21a) vaccine interact with other vaccines or antimalarials? ACIP agreed to recommend separation of receipt of Ty21 mefloquine by 24 hours.

6. Should parenteral influenza and pertussis vaccines be administered si or within 3 days of each other? Should document take a stand? Commi delete 3- day statement.

7. Can IPV be given under certain circumstances to pregnant women? Committee voted that one 1973 study that suggested malignancies might with this practice was no longer applicable for currently licensed vaccine

ACIP members also suggested the following: 1. address lapsed vaccinations; 2. section on vaccine interchangeability with all vaccines except Hib; 3. scrutinize contraindication table; 4. have a statement to the effect that "the first trimester should not be considered a contraindication to vaccination with tetanus toxoid."

Update on Immunization Levels of Pre-School Children

Ms. Elizabeth E. Zell, ID, NCPS, updated the ACIP on the immunization levels in 1991. Vaccination levels in this age-group have remained relatively constant except for measles, for which vaccination levels have increased to about 80% in However, only 37%-56% of these children were fully vaccinated with 4 DTP, 3 measles-containing vaccines. Over 90% of 3- to 11-month-old children had rece one vaccination.

Pre-Licensure Studies of Hib Conjugate-DTP Combinations

Dr. B. Fritzell from Connaught summarized safety and efficacy data on PRP-T presented data on the combination of PRP-T reconstituted with DTP. He said t controlled studies have shown that PRP-T/DTP is safe (reactogenicity is similar DTP and PRP-T given separately) and immunogenic (85%-96% have a PRP anti μg/mL). There were 43 adverse events in Finland (251,000 doses distributed), a 17.1/100,000 doses; in Canada, with 300,000 doses distributed in 1992, no severe reactions were reported except 1 case of high-pitched crying and 1 case of Hib hours of first vaccination. The FDA will be licensing in a two-step process: PR after review of data, the combination.

Dr. J. Haeckel from Lederle summarized safety and efficacy data on Lederle's c Haemophilus combination vaccine. She said that large-scale studies show that infants in a three-dose primary series is excellent. The immunogenicity of the equal to if not better than the separate administration of DTP and HbOC. The consistent, by lot, for all antigens.

Draft Statement on Hib Vaccine

Dr. Kenneth Zangwill, BD, NCID, said that since FDA will probably soon licens ıne of the above vaccines, a new ACIP statement for use of these vaccines might be neces y. He referred to two documents being drafted, including a broad update on Hib vacc es, and a working draft of an *MMWR* announcement of licensure of PRP-T vaccines, whi members had been given. The latter document recommends that PRP-T be given in the s ıe schedule as HbOC. He requested guidance about the issue of carrier priming. Dr. Zang l requested members to review the document (Handout #3) and send comments back to Ms ovach by March 19.

Draft ACIP Statement on DTP-HbOC

Dr. Roland Sutter, ID, NCPS, said CDC would also like to have an ACIP statem t available on DTP-HbOC as soon as it is released, and briefly went through a draft of one landout #4). His and the ACIP's biggest concerns were: 1) if a child started with one Hi vaccine, could he/she switch to another? and 2) whether the vaccine must really be give 2 months apart, especially for a child who starts his/her vaccination late. Dr. Carolyn Ha egree, FDA, agreed to look into whether data on the differences in efficacy between va inations spaced at 1-month compared to 2-month intervals could easily be teased out of sting data from manufacturers. Members were asked to return comments to CDC by Marc 19.

Follow-up on MSD Hib Conjugate

Dr. Jay Wenger, DBMD, NCID, updated the ACIP on Merck lots of Hib conjuga vaccine that had produced less-than-optimal seroconversion rates. Merck has distribute 20,000 doses of vaccine to revaccinate children receiving these lots, much less than the),000 they thought they'd need. Phone responses to their announcement of suboptimal lot ave also been much less than expected. No additional cases of Hib associated with the q stionable lots of vaccine have been reported.

Safety of Simultaneous Vaccination: Analysis of VAERS Data

Dr. Robert Chen, ID, NCPS, said there has been some concern about safety of si ltaneous administration of Hib and DTP vaccines in infants. Dr. Gail King, ID, NCPS, re wed prelicensure data that demonstrated that giving Hib conjugate vaccines together ith other infant vaccines is a safe practice. However, CDC will continue to monitor safet ı actual use in larger numbers of children, including phase IV trials, analysis of VAERS a, and systemic examination of specific events through the large, linked databases.

Mr. John Mullen, ID, NCPS, briefly reviewed the history of post-marketing surv ance for vaccine adverse events. Some 800-1,200 reports are now received a month throu ı VAERS, for a total of 22,000 thus far. He then presented a preliminary analysis on the is es of safety of simultaneous administration of DTP and Hib. There has been no increase in ported rates of hospitalization and death following DTP vaccination given simultaneou with Hib compared with DTP given alone. Additional analyses are under way to examin eizures and prolonged crying to see if any specific diagnoses stand out.

Dr. Chen then discussed future analyses and directions in VAERS. He explainec ıat VAERS, although useful for examining ecologic trends and generating hypotheses, in mc instances cannot assess whether a vaccine actually caused an adverse event. He said that ntrolled studies are needed to test hypotheses. One involving large-linked database (LL) studies at four HMOs is under way. By 1995, these LLDB should be able to detect associa ns between rare events that occur in 1/100,000 to 300,000 doses.

Hepatitis B Vaccination Programs

Mr. James Mize, ID, NCPS, discussed the implementation of the hepatitis B vac e program in various states. He said that a recent CDC survey reveals that 82% of immun tion programs have a universal hepatitis B program. Most (53%) give HB-1 at birth. lost projects are giving hepatitis B with other injections, as opposed to scheduling a tional visits. Two-thirds of immunization projects are using carryover balances of fed l, state, and local funds to support their universal immunization programs and are not ving to make arbitrary decisions about whom to vaccinate.

Diphtheria--Russia

Dr. Melinda Wharton, ID, NCPS, summarized the current diphtheria epidemic i Russia, which she recently visited. There were an estimated 4,000 such cases in the Ru ın Federation in 1992, concentrated in large urban areas. This rate is puzzling bec se,

officially, vaccine coverage is high. CDC will collaborate on a microbiologic stu to characterize circulating strains, and a vaccine efficacy study has been initiated.

The meeting closed for the day at 6:00 p.m. It began on February 10 at 8:00 a.m

Influenza

Dr. Nancy Cox, VR, NCID, discussed international influenza activity and the an enic characteristics of recent influenza viruses. These set the context for the influenz vaccine strain recommendations that were made by the FDA Vaccine Advisory Panel, w ch met in Washington on January 26. Worldwide, it is a quiet influenza season. Influenz is predominating in Europe and North America. Japan, which has an extensive su eillance system, has found that half of their 450 isolates are influenza A(H3N2) and half fluenza B. The recommendation for the B component for the influenza vaccine for the 199 season is B/Panama/45/90. The final recommendations for the A(H3N2) and A(H1N1) c mponents are being deferred until additional data are available and WHO makes its annu vaccine recommendations during the week of February 15.

Dr. L. Simonsen, VR, NCID, described the U.S. surveillance system in the Unite tates and said that, thus far, the 1992-93 flu season has been quite typical for a B season, h less morbidity and no detectable influenza-related mortality observed so far on the ional level.

Dr. Nancy Arden then went over changes in the draft ACIP statement preventi and control of influenza (Handout #5). By vote, the ACIP agreed to delete the phrase on p. that "vaccine cannot cause influenza"; to accept the bold-face new paragraph on p. 4 garding the effectiveness of the vaccine (except to make it two paragraphs); to modify recor endation #1 on p. 6 to recommend flu vaccination for all hospital personnel, not just high sk ones; to change the phrasing regarding students on p. 8 by deleting the phrase about dc itories and by encouraging vaccination with a caveat about "depending upon resources ava ble" to modify the paragraph on p. 8 about pregnant women by deleting the second-to st sentence, and changing the last sentence to state "regardless of the stage of pregnancy."; t lelete the phrase "but those at highest risk of fatal pneumococcal disease" from paragraph on p. 11 and the last sentence of the next paragraph; on p. 10, to delete the sentence in ragraph 3 on "warfarin and theophylline" and substitute a sentence to the effect that there re no increased adverse reactions among asthmatics"; and, on p. 15, to soften the reco nendation that Amantadine be administered "to all health-care providers" in outbreak situ ons and to provide more extensive revision on toxicity. (Dr. Hardegree also requested that DA's antiviral section have a chance to look at this document because of the possibili of new warnings for the package inserts for Amantadine).

There was some discussion about issuing a recommendation to vaccinate all stu nts against influenza, but the group voted that they were not ready to recommend that as ublic health measure. Dr. Katz suggested it be put on the agenda for a subsequent m ting, that Dr. Ted Eickhoff be invited to speak about whether people who get annual sho nave different responses to vaccines, and to revisit the goals of the influenza vaccina n program.

Dr. Arden said that CDC hoped to publish the flu document by May in the *MM* 'R. It was suggested that the flu document be published in May but the ACIP statement c Amantadine (Handout #6) be delayed until next fall. The ACIP voted to endor :his idea.

Dr. Chen described the final analysis on the possible association of GBS and flu ıccine during the 1990-91 season. Data suggest that a 15- to 64-year-old at high risk o ıfluenza would have a low risk (5 in a million) of getting GBS from the vaccine that yea ıut at the same time would reduce the risk (1/10,000) of dying from influenza if not prot ɛd by vaccine. Thus, for the high-risk population of 18- to 64-year-olds, the benefit cl ly outweighed the risk. For the low-risk population in this age-group, there was a ılanced risk-benefit ratio. Dr. Chen also asked for approval of changes to his document nnex #3, mailed to members, regarding the GBS findings. The group voted, 8-to-7, on o motion (option D) but since this vote was so close, discussion reopened and ended in t assignment of an ad hoc committee, composed of Dr. Clements, Dr. Halsey, Dr. Mortimer, a l Dr. Chen, to come up with acceptable wording.

Group C Meningococcal Meningitis Clusters

Dr. Lisa Jackson briefly updated the group on the recent Canadian experience v ı increased cases of this disease, and discussed the occurrence and management of outbrea ɔf this disease in the United States. The last ACIP statement on the vaccine for this di se was in 1985. Dr. Jackson asked the ACIP to determine whether, in the 1985 ACIP stat ent on this subject: 1) the methods of defining an outbreak and instituting vaccination are a ɔropriate; and 2) there is a need for more specific ACIP recommendations for the manage nt of group C outbreaks? Dr. Katz said the Committee was not prepared to revisit this stat ent now, but asked that the subject be added to a future agenda and suggested revisions mailed out in advance.

Injury Compensation Update

Mr. T. Balbier, Jr., from the National Vaccine Injury Compensation Program, sa hat a review of that program had just been completed and submitted to Congress. It as very favorable regarding operations and management, but noted that resources are i ıfficient. Steps have been taken to implement the two recommendations made by the pr am review to HHS. A proposed revision of the Injury Compensation Table has been publi ɛd, and a public hearing held. He also noted that there is a new number for the U.S. Co of Federal Claims: 1-202-219-9657. Regarding the Internal Revenue Code provisions for va ne excise taxes, he said the Secretary of the Treasury has authority to terminate the excis x, as of January 1, 1993, and he did so; thus, no additional funds are going into the con nsation trust fund.

After his presentation, Dr. Katz read a statement (Handout #7) from Dr. Ken Ba who was unable to attend, about the new Administration's proposals regarding immuniz ɔn, including an immunization registry and recall system and federal purchase of a he recommended childhood vaccines. Because of concerns about the latter's effect pon the vaccine industry, a public hearing is scheduled for February 24. Dr. Katz, who ll speak at it on behalf of the ACIP, asked for direction on what to say. Topics brought u ere to

mention adult vaccines, the need for flexibility in the system, and the importanc f the registry and tracking system.

Polio in the Netherlands

Dr. Frederik Van Loon, ID, NCPS, summarized the recent polio outbreak in the therlands. A total of 67 cases (all but one in a religious, unvaccinated group) have been re ted. The outbreak, which does not appear to have spread to the general population or to ner countries, has apparently slowed down dramatically.

Update on the BCG Meta-analyses

Dr. Lawrence Geiter, TB, NCPS, briefly reviewed the BCG meta-analysis project, hich was awarded to the Harvard School of Public Health in September. The objectives o he analysis were to review the literature on the efficacy of BCG in humans, to assess the qu y of available data, and to report back on the feasibility of a meta-analysis. Their fir eport just came in. A total of 70 reports and abstracts on the subject have been identified. garding health-care workers (HCWs), 12 studies adequate to review have been located; 7 ave been reviewed--enough to provide a narrative summary, at the least, and possibly a r a-analysis. The Harvard School is not confident about its ability to look at efficacy by vacci strain. Data are also very sparse for efficacy in adults; the group questions that a meta- alysis can be done by age-group and suggests a narrative summary instead. The final rep from Harvard is due in May or June.

Potential Future Adult Immunization Issues

Dr. Pierce Gardner said that if the currently recommended vaccines for adults v e fully utilized, 35,000 deaths would be prevented each year. He said that the consens of experts he has consulted is that the recommended age of immunization for pneumococ vaccine should be reduced; if it were given at 55 years or age instead of 65, the immune sponse and duration of that response would be longer. Secondly, he urged that a cost- nefit analysis be undertaken to see if a single, mid-life tetanus-diphtheria toxoid boos would be better than the currently recommended every 10-year booster. Third, he said th the Amantadine recommendations are too broad and are ignored by practicing phy ians. Concerns of physicians--about the toxicity of the 100-mg dose, uncertainly of di noses of influenza, and uncertain benefits in the face of severe complications--need to be nsidered. Finally, some are wondering if post-immunization serologic testing should be r ine, at least for certain target groups.

Dr. Katz asked that the next agenda have a section on adult immunization, incl ng representatives on prisons and colleges. He also asked Dr. Gardner to pull toge r data from the pending Task Force on Adult Immunization Green Book Committee meetin nd present it at the June ACIP meeting.

Dr. William Schaffner urged that the ACIP recommendations be simpler and cl er. He also said they also need to be marketed as a product, not simply published in the *M WR*.

Immunization for HCWs: Review of ACIP Recommendations

Drs. Ray Strikas, ID, NCPS, Miriam Alter, VR, NCID, and Craig Shapiro, VR, N), discussed Immunization Recommendations for HCWs (Handout #8) and a revis of the BCG section (Handout #9). Dr. Alter discussed the issue of postvaccination test for hepatitis B surface antibody. One member suggested that the document should ntain more liberal recommendations for postvaccination testing of HCWs. Dr. Alter stated t this document should be consistent with the most recently published ACIP recomm lations on hepatitis B vaccine issued in November 1991. Dr. Alter noted that regarding us f immunoglobulins for prevention of hepatitis C following needlestick accidents, draft HCW document now states (on p. 28) that new recommendations can't be made id reiterates previous recommendations that high-dose immune globulin be consic ed.

Dr. Shapiro discussed hepatitis A immunoprophylaxis for HCWs. He said that tbreaks of hepatitis A have occurred among HCWs, and that when they have, immune glo lin has been effective in preventing further transmission. However, based upon seropr lence data, the occupational risk of hepatitis A to HCWs in general appears to be low. The ore, whether hepatitis A vaccine should be used in HCWs has not yet been determir .

Dr. Strikas then led a discussion centered around several questions. It was decic to add a line to the effect that "arthropathy following rubella vaccine has been the subjec f considerable study and the reader is referred to. . ." It was decided not to add tions on needlestick injuries or medical students. Regarding MMR vaccine's being reco ended when any of the three individual antigens would be recommended but only M is available, the Committee decided that the current statement (p. 19) is not as per ssive as the ACIP wants. Dr. Katz asked Dr. Strikas to have that section redone. The ACIP so decided to insert specific ACIP recommendations about varicella vaccine if the vaccine i censed. Relatedly, the ACIP voted that normal but serosusceptible HCWs should not ro nely be given VZIG. In addition, a brief mention of the role, if any, for antiviral (e.g., a lovir) treatment of varicella should be included. Regarding polio, the ACIP decided t elete the hospital requirements for polio vaccination of HCWs (except for caveats about a mported case or outbreak; see pp. 31-32) and to list polio vaccination under foreign trave It was also decided to omit the rabies section and mention it under foreign travel.
Any other comments on this document were requested within 6 weeks.

Report of Ad Hoc Committee on Statement Regarding GBS within Influenza **tement**

Dr. Clements then presented the revised statement on GBS:

> Unlike the 1976-77 swine influenza vaccine, subsequent vaccines prepare from other virus strains have not been clearly associated with an increas frequency of Guillain-Barre syndrome. However, it is difficult to make a precise estimate of risk for a rare condition such as GBS. In 1990-91, alt igh there was no overall increase in frequency of GBS among vaccine recipie , there may have been a small increase in GBS cases in vaccinated person 3 to 64 years of age, but not in those 65 years or older. In contrast to the swi influenza vaccine, the epidemiologic features of the possible association he 1990-91 vaccine with GBS were not as convincing. Even if GBS is a true le effect, the very low rate would be more than compensated by disease prevented by the vaccine.

The group voted to accept this statement.

General Recommendations on Immunization

Dr. Watson went over suggested changes to this ACIP Statement (Handout #2). he group voted to delete the section on "Future Vaccines and Vaccination Schedules" on) 38. The group also voted that the paragraph on polio vaccination during pregnancy (pp 33-34) should be redone to clarify about killed and live-virus vaccines. Regarding jet i ctors, the ACIP accepted, with minor changes, Dr. Watson's revised sentences on this sub t except that they decided that indications of "higher prevalence" areas (when jet injecto would be recommended) should be defined by examples (e.g., needle-using drug-users), l not by rates or numbers. It was also suggested that a sentence be added to the effect t "before embarking on a mass immunization program using jet inoculation, consult thos who have had experience." Regarding the issue of the interchangeability of vaccines, this is noted to be acceptable for DTP/DT/DTaP and for hepatitis B vaccines, when indicated; wever, it was decided that further data are necessary for Hib vaccines. Finally, regardin ne issue of whether steroids cause sufficient immunosuppression to cause severe reactions live-virus vaccines, the ACIP voted to 1) keep the current language in the revised handou and 2) to include a statement that although theoretical concerns have been raised, there a no published data to support increased severe reactions to vaccine in these person herefore, vaccination should not be delayed.

Immunization of Bone Marrow Transplant Patients

Dr. Hadler, replacing the scheduled Dr. M. Grabowsky, said that 20 experts on ne marrow transplantation were sent draft copies of an ACIP statement on this subject, anc nly 6 replies were received. He asked the Committee if an ACIP statement on this s ect should be jointly authored by the ACIP and the American Society of Hematology or if nor issues should be resolved and it should be published as an ACIP statement. Dr. Katz id for the time being, not to go forward with the statement and that he would take the re onsibility for finding a group to liaison with on the statement.

Before closing, Dr. Katz asked for public comment. There was none. Members en requested that the June 2-3 ACIP meeting begin at 1:00 instead of the morning. this can be arranged, it will be. Dr. Gardner also said that he would send 25 copies of the een Book to Ms. Kovach to distribute to ACIP members and liaisons. The meeting adjou d at 3:40 p.m.

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

Samuel L. Katz MD

Samuel L. Katz, MD, Chairperson Date: 27 April 73