

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL

MINUTES OF MEETING

Immunization Practices Advisory Committee
September 10, 1984
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Room 207 at the Centers for Disease Control, Atlanta, Georgia, on September 10, 1984. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

Dr. James Chin, Chairman
Dr. Ellen S. Alkon
Mrs. Betty F. Bumpers
Dr. David S. Fedson
Dr. Anne A. Gershon
Dr. Donald A. Henderson
Dr. Samuel L. Katz
Dr. Joan K. Leavitt
Dr. Edward A. Mortimer
Dr. William Schaffner II

Ex Officio Members

Dr. William S. Jordan, Jr. (NIH)
(represented by Dr. D. L. Klein)
Dr. Harry Meyer, Jr. (FDA)
(represented by Dr. Elaine Esber)

Liaison Representatives

Dr. Philip A. Brunell (AAP)
Dr. Jarrett Clinton (DD)
Dr. J. M. S. Dixon (NACI)
Dr. Theodore C. Eickhoff (ACP)
Dr. Albert W. Pruitt (AMA)

Executive Secretary

Dr. Jeffrey P. Koplan

HHS STAFF PRESENT

FOOD AND DRUG ADMINISTRATION

Center for Drugs and Biologics
Dr. Elaine Esber

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy
and Infectious Diseases
Dr. David L. Klein

HHS STAFF PRESENT (continued)

CENTERS FOR DISEASE CONTROL

Office of the Director

Mr. Donald A. Berreth
Mr. Gene W. Matthews
Ms. Verla Neslund
Ms. Gwendolyn Strickland-Cid
Mr. William C. Watson

Center for Infectious Diseases

Dr. Kenneth W. Bernard
Dr. Claire V. Broome
Dr. Steven L. Cochi
Dr. Walter R. Dowdle
Dr. Mark A. Kane
Dr. Jack D. Poland
Dr. Larry B. Schonberger

Center for Prevention Services

Dr. Kenneth J. Bart
Dr. Roger H. Bernier
Mr. Windell R. Bradford
Dr. Edward W. Brink
Dr. J. Michael Lane
Dr. Benjamin M. Nkowane
Dr. Ida M. Onorato
Dr. Walter Orenstein

International Health Program Office

Dr. Myron G. Schultz

HEALTH RESOURCES AND SERVICES ADM.

Bureau of Health Care Delivery
and Assistance
Dr. Allan Noonan

OTHERS PRESENT

Dr. Gary J. Bridi
Colonel Alfred K. Cheng (USAF)
Dr. Pinya Cohen
LCDR David E. Conwill, MC, USN
Ms. Gloria Conwill
Dr. H. Bruce Dull
Dr. Alan H. Goldschein
Dr. Steffen Gruhn
Dr. Harry Guess
Dr. Marc Gurwith
Dr. Jill G. Hochell
LTC James Kirkpatrick

Dr. Saul Krugman
Dr. Donald W. McCoy
Dr. Arlene McLean
Dr. Don Metzgar
Dr. Douglas B. Reynolds
Mr. Tom Sellers
Dr. Mason G. Stout
Dr. Ronald J. Vallancourt
Dr. Ralph A. Vosdingh
Dr. Richard F. White
Dr. Timothy Williamson
Dr. Paul Wilson
Dr. Barbara A Zajac

The Fall meeting was opened at 8:30 a.m. on September 10, 1984, by the Chairman Dr. James Chin. Dr. Chin welcomed members of the Committee and others present and introduced Mr. William C. Watson who will retire as Deputy Director of the Centers for Disease Control on October 1, 1984. Mr. Watson welcomed the Committee members. Dr. Chin introduced two new Committee members, Mrs. Betty F. Bumpers from Arkansas and Washington, D.C., and Dr. David S. Fedson from the University of Virginia Medical School. Dr. Chin also introduced Dr. Albert W. Pruitt, Medical College of Georgia, new liaison representative of the American Medical Association. Dr. Elaine Esber represented FDA for Dr. Harry Meyer, and Dr. D. L. Klein represented NIH for Dr. William S. Jordan, Jr.

Poliovirus Vaccines

Dr. Kenneth Bart, Division of Immunization, Center for Prevention Services, CDC, gave introductory comments on inactivated polio vaccine (IPV) versus oral polio vaccine (OPV). Dr. Benjamin Nkowane presented an update on paralytic poliomyelitis. He reviewed polio incidence rates and death rates per 100,000 population in the United States from 1960-1983 and epidemiologic classification of the best available paralytic polio case count from 1972-1983, contact vaccine-associated paralytic poliomyelitis from 1972-1982, and estimated risks for vaccine-associated poliomyelitis per doses of OPV distributed in the USA from 1972-1983. Dr. Roger Bernier gave comparisons of three different vaccines in children with detectable polio neutralization antibodies by virus type, and reciprocal geometric mean titers of polio neutralization antibodies as well as percent of children with detectable Type I, Type II, and Type III polio neutralization antibodies by age and study group. The data provided evidence that the risk of vaccine associated injury is small. A decision analysis of OPV and IPV use should be available by the next Committee meeting.

Varicella-Zoster Vaccine

The results of a study of clinical varicella in vaccine recipients and vaccinees with household exposure to varicella were given by Dr. Anne Gershon. Dr. Philip Brunell discussed types of antibody response to the initial dose of varicella vaccine, response to reimmunization, results of household exposure, and varicella in vaccinees with leukemia.

Japanese B Encephalitis

Dr. Jack Poland, Division of Vector-Borne Viral Diseases, Fort Collins, reviewed the current status of Japanese encephalitis (JE) vaccine evaluations. In commenting on the results, Dr. Poland stated that because serologic response to a 2-dose schedule of Biken JE vaccine was inadequate, approval was obtained from CDC's Investigational Review Board to alter the study protocol to evaluate a 3-dose primary series schedule which was initiated early this year. The level of serological response is quite gratifying. Of the first 66 participants of the 3-dose schedule, 65 (99%) responded with seroconversion of ≥ 32 , and 64 had titers of ≥ 64 . Data on persisting antibody 1 year later and the effect of a single booster dose at 1 year should be available in mid-1985. Comparable results and conclusions were obtained on 75 participants serologically evaluated from among 1,000 vaccinees, primarily British workers, in a Nepalese study comparing 2- and 3-dose schedules.

Meeting Summaries

Dr. Bart reported on the National Immunization Conference held May 21-24, 1984, in Boston.

Dr. Elaine Esber, FDA, stated that a representative from ACIP (Dr. Mortimer) and from the Red Book participated in the FDA Vaccine Advisory Committee on DT Dosage, June 8, 1984. Pertussis statements, DT vaccine doses, and manufacturing labeling were discussed.

Dr. Esber announced the following meetings:

- September 17-20, 1984 - IV International Bacterial Vaccine Symposium, to be held on the NIH Campus
- September 20-21, 1984 - Workshop on Pertussis Toxins, NIH Campus
- September 25-27, 1984 - IV International Symposium on Pertussis, Geneva, Switzerland

Hepatitis

Dr. Arlene McLean, Merck Sharp and Dohme Research Laboratories, presented information from Dr. Bernard Poiesz's research at State University of New York on the inactivation of retroviruses HTLV-1 and HTLV-2 (human T-cell leukemia virus) in transformed lymphocytes by the inactivation procedures used in the preparation of MERCK hepatitis B vaccine. All three inactivation procedures (pepsin, urea, and formalin) were independently applied to the viruses, and in all cases he found no transformation in the standard transformation assay. Experiments with lymphadenopathy associated virus (LAV), the virus thought to be the etiologic agent of AIDS, will be completed within a few weeks.

An independent study looking for HTLV-1 nucleic acid in various vaccine preparations showed none down to one picogram per 20 mcg. vaccine.

HTLV-1 or HTLV-2 antibody was not detected in sera of vaccine recipients.

Dr. Fred Shaw, Division of Viral Diseases, gave an update on hepatitis B vaccine safety, stating that there are no reported cases of AIDS in vaccine recipients who are not either male homosexuals or parenteral drug users. Other serious side effects have not occurred frequently enough to cause alarm. Dr. Shaw stated that 7 cases of Guillain Barre Syndrome (GBS) occurred in vaccinees within 6 weeks of a vaccine dose. Given an estimated 650,000 vaccine recipients, and a background range of GBS in the population of 15/1,000,000 to 23/1,000,000 per year, we are still within the 95% C.I. of the expected number of cases by the Poisson distribution. This merits careful monitoring in the future, but it should be pointed out that even if an association between GBS and the vaccine should emerge, the amount of hepatitis B related disease prevented by the vaccine would make it unlikely that we would change our vaccine recommendation.

Dr. Mark Kane, Division of Viral Diseases, led a discussion of a revised draft of the 1981 statement, "Immune Globulins for Protection Against Viral Hepatitis," that was mailed to the Committee for their review prior to the meeting. The draft also incorporates the recently issued (June 1, 1984) recommendation "Postexposure Prophylaxis of Hepatitis B," placing all relevant ACIP recommendations on immune globulins in one statement. Changes include modified recommendations for day-care workers and foodhandlers, and prophylaxis on hepatitis A for travelers. Dr. Chin ask Committee members to return written comments on the draft to Dr. Koplan within 2 weeks.

After a discussion, the Committee agreed that even though hepatitis B vaccine is not as effective in dialysis patients as in persons with normal immune systems, the ACIP still recommends its use in dialysis patients.

Pertussis and Pertussis Vaccines

Dr. Kenneth Bart distributed a revised draft of the August 1981 statement "Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures." The draft includes an update of the April 1984 "Supplementary Statement of Contraindications to Receipt of Pertussis Vaccine." Dr. Chin asked the Committee to return their comments to Dr. Koplan within 2 weeks.

Other Items Discussed

Dr. Walter Orenstein summarized the present status of measles. During the first 26 weeks of 1984, 1,759 cases were reported in the United States, representing a 60.6% increase from the 1,095 cases reported during the same period in 1983. Although the overall incidence rate increased, the number of States reporting measles decreased during the first 26 weeks of 1984, compared with the same period of 1983; 24 States reported no measles cases compared with 22 States and the District of Columbia during the same period in 1983. In 1983, the highest incidence rates were reported for preschool children. In contrast, the rates for the first 26 weeks of 1984 were greatest for children 10 to 14 years of age. A discussion was held regarding the concern for criteria for physician-diagnosed measles.

Vaccine Compensation

Dr. J. Michael Lane, Director, Center for Prevention Services, CDC, summarized a history of immunizations and compensation/liability.

The Committee discussed the need for a system of compensation for vaccine-related injuries and the fact that vaccine manufacturers have become discouraged and many have discontinued vaccine manufacture. The Committee also discussed the need for a national compensation system so that persons immunized in the public interest could be compensated in the event of injury. The Committee will review a draft document on compensation, being prepared by the Institute of Medicine, and other related reports and proposals.

Haemophilus Influenzae

Drs. Broome and Cochi, Division of Bacterial Diseases, CID, gave data on H. influenzae type B (HIB) polysaccharide vaccine. Discussions were held on the efficacy and immunogenicity of the vaccine, recommendations for the use of vaccine at 18 months versus 24 months of age, day care attendance and risk of primary HIB disease in the Istre case-control study in Colorado, use of HIB vaccine in children above 24 months and the age for initial vaccine, and revaccination. The polysaccharide vaccine may be available by the end of this year.

Dr. Chin asked the subcommittee, appointed during the April 1984 Committee meeting, (Drs. Mortimer, Katz, and Leavitt) to work with Dr. Broome's staff to draft a statement for the Committee to review during the next meeting in January 1985.

Dr. David Klein, National Institute of Allergy and Infectious Diseases, NIH, summarized an efficacy field trial study and gave the status of a conjugate vaccine which may be licensed in approximately 2 years. Dr. Chin asked for a summary of the Day Care Symposium.

Other ACIP Business

The next Committee meeting was scheduled for January 31-February 1, 1985. Tentative agenda items will include Haemophilus influenzae, vaccine compensation, hepatitis B, and varicella vaccine.

With the thanks of the Chairman, the meeting was adjourned at 5 p.m.

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

James Chin
James Chin, M.D.

Oct 5 1984
Date