DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL

MINUTES OF MEETING

Immunization Practices Advisory Committee
May 12-13, 1986
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control, Atlanta, Georgia, on May 12-13, 1986. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

Dr. Samuel L. Katz, Chairman
Dr. Ellen S. Alkon
Dr. Jeffrey P. Davis
Dr. David S. Fedson
Dr. Anne A. Gershon
Dr. D. A. Henderson
Dr. Joan K. Leavitt
Dr. Edward A. Mortimer
Dr. William Schaffner II

Ex Officio Members

Dr. William S. Jordan, Jr. (NIH)
Dr. Elaine Esber (FDA)

Liaison Representatives

Dr. Philip A. Brunell (AAP)
Dr. John Herbold (DOD)
Dr. J. M. S. Dixon (NACI)
Dr. Albert W. Pruitt (AMA)

Executive Secretary

Dr. Jeffrey P. Koplan

COMMITTEE MEMBERS ABSENT

Mrs. Betty Bumpers

Liaison Members

Dr. Theodore C. Eickhoff (ACP)

HHS STAFF PRESENT

CENTERS FOR DISEASE CONTROL

Office of the Director

Dr. Robert Amler
Dr. John E. Jaugstetter
Mr. Gene Matthews
Dr. Gary Noble
Ms. Gwen Strickland-Cid

HHS STAFF PRESENT (continued)

CENTERS FOR DISEASE CONTROL (continued)

Center for Infectious Diseases

Dr. Mitchell Cohen
Dr. James Curran
Dr. Daniel Fishbein
Dr. Stephen Hadler
Dr. Kenneth Herrman
Dr. Margaret Oxtoby
Dr. Steven Redd
Dr. Martha Rogers
Dr. Leigh Sawyer

Center for Prevention Services

Mr. Steven Barid
Dr. Roger Bernier
Dr. Robert Chen
Dr. Steven Cochi
Dr. Ronald Davis
Mr. Thomas DeMarcus
Mr. Bill Doyle
Mr. Carl Hawkins
Dr. Alan Hinman
Dr. J. Michael Lane
Dr. Lauri Markowitz
Mr. Dean Mason
Mr. John Mullen
Mr. Dennis O'Mara
Mr. Jim Mize
Dr. Ida Onorato
Dr. Walter Orenstein
Dr. Peter Patriarca
Dr. Harrison Stetler
Dr. Walter Williams

Epidemiology Program Office

Dr. Robert Gunn

International Health Program Office

Dr. Kenneth Bernard
Dr. Michael Deming

OTHERS PRESENT

Dr. Salim Akrabawi
Ms. Dianna Anderson
Dr. Norman Begg
Mr. Gary Bridi
Dr. B. Brock
Dr. Kenneth Brown
Mr. Robert Byrd
Ms. Leslie Chapman
Mr. Robb Chapman
Ms. Kathleen Clark
Ms. Karen Booker Cline
Dr. Pinya Cohen
Dr. Larry Cummins
Commander Mark Dembert
Mr. Ingram Douglas-Hall
Ms. Ellen Duff
Mr. Russell L. Durbin
Dr. Bruce Dull
Ms. Carol Estes-Youorski
Mr. Stu Feldman
Ms. Barbara Loe Fisher
Ms. Judith Glomb
Dr. Jill Hackell
Mr. Russ Jamison
Dr. Victor Jegede
Dr. Andre LaMotte
Mr. Bruce Lesser
Mr. David McCutcheon
Dr. Margaret McLauhglin
Mr. J. A. Morris
Ms. Patricia Patrick
Ms. Becky Peterzell
Ms. Debbie Pulley
Mr. Michael Rodee
Mr. Myron Rodee
Dr. Terry Rooney
Dr. Zeil Rosenberg
Dr. Jane Scott
Mr. Russell Shaw
Dr. David Smith
Mr. Tory Smith
Dr. Rick Steeves
Dr. Cladd Stevens
Dr. Mason Stout
Lt. Col. Ernest Takafuji
Ms. Patricia Thomas
Dr. Mark Weeks
Dr. Richard White
Ms. Kathi Williams
Dr. Paul Wilson
Dr. A. F. Woodhour
Ms. Mary Wyatt

The meeting was opened at 8:30 a.m. on May 12 by Dr. Samuel L. Katz, Chairperson. Dr. Elaine Esber represented Dr. Harry Meyer, Jr., FDA, and Dr. John Herbold represented Dr. Jarrett Clinton, Department of Defense.

Dr. James O. Mason, Director of CDC, presented letters and certificates to Drs. D. A. Henderson, Joan K. Leavitt, and William Schaffner in appreciation of their assistance and advice as members of the Committee from July 1982 to June 1986.

Measles Elimination

Dr. Alan Hinman, Division of Immunization (DI), Center for Prevention Services (CPS), CDC, introduced a series of presentations by the staff of DI intended to brief the Committee on measles incidence in the United States for 1984-1985. This included data on the number of cases of measles and the percentage of preventable cases, age distribution and estimated incidence rates, age distribution and preventability of measles cases, and reasons measles cases were classified as nonpreventable by age groups. Dr. Lauri Markowitz reviewed clinical case definitions as well as strategies and options for immunization schedules, and presented data from serologic and

epidemiologic studies on duration of measles vaccine-induced immunity. Dr. Ronald Davis reviewed epidemiology in the United States for 1984-1985; reported on serologic studies on the effect of age at vaccination of measles vaccine-induced immunity; cohort and case-control studies (12 months of age vs. older ages) of age at measles vaccination and clinical effectiveness; and studies comparing one dose of measles vaccine vs. multiple doses.

The measles outbreak in New Jersey was discussed. The outbreak which began in November 1985 is the largest U.S. measles outbreak since 1983; it differed from most outbreaks in that a large proportion of cases occurred among preschool-aged children, instead of high school or university students. The source of infection in the index patient, a 2-1/2-year-old Hispanic child, is unknown. It appears that the size and extent of this outbreak reflect a large pool of susceptibles in the preschool-aged population, and this has probably contributed to the spread of measles to children under 16 months of age.

Dr. Katz appointed a subgroup (Drs. Jeffrey Davis, Philip Brunell, and Anne Gershon) to work with Dr. Walter Orenstein to prepare a draft update on measles prevention.

Hepatitis B Vaccine - Post-Vaccination Considerations

Dr. Stephen Hadler, Division of Viral Diseases, Center for Infectious Diseases (CID), CDC, addressed specific issues regarding duration of protection and need for booster doses of hepatitis B (HB) vaccine. He presented data on long-term protection from HB vaccine, including antibody persistence, protection against infection, and revaccination of nonresponders. He also led a discussion on need for booster doses, considerations for booster-dose strategy, including effectiveness in cost, feasibility, and acceptability; comparison of costs and effectiveness of HB vaccination and two booster-dose strategies every 7 years; and comparison of booster doses at 5-, 7-, and 10-year intervals. Dr. Hadler suggested that the most cost effective strategy would be to give regular booster doses every 5 or 7 years without serologic testing and that the cost effectiveness of revaccination is dependent on the proportion of nonresponders and relative costs of vaccine and laboratory testing. For present, vaccination should be recommended for hemodialysis patients, persons who received initial vaccine in the buttock, and other groups with expected low response to vaccine series.

Dr. Cladd Stevens, New York Blood Center, presented antibody data from studies at 5 years in HB vaccine recipients (homosexual men and dialysis staff); presented data and discussed hepatitis B virus (HBV) infections in homosexual men who responded to Merck HB vaccine, antibody to HBsAg (anti-HBs) response following primary immunization with plasma-derived HB vaccine and a subsequent booster dose of yeast recombinant HB vaccine 5 to 7 years later, and immunogenic effect of a booster dose of HB vaccine administered 6 years after initial immunization.

Dr. Katz asked Dr. Hadler to prepare a draft recommendation on post-vaccination of hepatitis B vaccine to be discussed at the fall ACIP meeting.

Pertussis

Following lunch, the next 2 hours were devoted to specific subjects addressed by the Committee and representatives of Dissatisfied Parents Together (DPT). The topics discussed were:

I. Vaccine Associated Deaths

- o Definitions of "vaccine related death"
- o MSAEFI system (Monitoring System of Adverse Events Following Immunization)
- o Education of physicians on symptoms of vaccine reactions

II. Informal Survey of Reactions in Family Members

III. Vaccine Efficacy and Recent Pertussis Outbreaks

IV. DTP Availability

Ms. Kathi Williams, Director of DPT, gave the introduction, stating that the group represents parents who want to protect children from vaccine reactions as well as childhood diseases.

In the opening statement, Ms. Barbara Loe Fisher, Vice President of DPT, expressed concern over a recent suspension of DTP vaccinations in France reportedly related to deaths in infants. France has subsequently resumed DTP immunization, after withdrawing two lots of vaccine from the market. Ms. Fisher stated that the DPT group is concerned about the relationship of the infant deaths to pertussis vaccine.

Mr. David McCutcheon of Rye, New York, gave a report of his 20-month-old son's death 8 hours after receiving DTP. Ms. Dianna Anderson of Cambridge, Illinois, gave a report of her daughter's death 33 days after receiving DTP. Mr. Michael Rodee from Emporia, Kansas, gave a report of his 6-month-old son's death 96 hours after receiving his third DTP.

Mr. Robb Chapman, Atlanta, Georgia, asked for a better reporting system of vaccine-related deaths. He stated that most vaccine-related deaths are not reported to the MSAEFI system. Mr. Chapman proposed (1) that a new category, "suspected pertussis vaccine deaths," be added in the reporting system (definition for this category, "a child receives a DTP shot, exhibits one or more CDC acknowledged acute, severe reactions within seven days and begins a mental and/or physical deterioration, culminating in death"); (2) that a nongovernment panel of experts determine which cases fit these criteria; (3) that it be mandatory to report all severe events following immunization in both the public and private sectors; (4) that efforts be made to educate medical professionals, parents, and coroners about severe reactions. Finally, he stated that thoroughly educated coroners are a vital link in the proposed system and, given the guidelines and the mandate to report, they could provide key evidence for or against the vaccine's role in deaths where DTP is suspected.

Ms. Judith Webb Glomb, President of the Pennsylvania Chapter of DPT, requested that plain language be included in the MSAEFI report form, that names of children be listed on the form, and that public health clinic doctors and nurses be educated regarding adverse reactions following immunization. Ms. Karen Booker Cline, President of the Oklahoma Chapter of DPT, gave data she had collected on "Families with Multiple DTP Reactions," and she asked that a family history of severe reactions to DTP as a contraindication to receipt of pertussis vaccine be included on the MSAEFI report form.

Ms. Fisher discussed "Whooping Cough in America's Vaccinated Population," and described persons who had received DTP vaccination but also developed whooping cough. She stated that it is difficult to evaluate pertussis morbidity and mortality statistics provided by State health departments because each State has different criteria for what information is gathered as well as how that information is tabulated and reported. It would be useful if CDC could develop guidelines for the States and encourage uniform gathering and tabulation of pertussis data. Ms. Fisher and Ms. Leslie Chapman discussed their knowledge of the Japanese acellular pertussis vaccine.

Regarding the vaccine associated deaths, Dr. Katz asked for a clarification from the DPT of the definition of severe adverse reactions (e.g., degree of temperature, etc.).

After listening to the DPT's statements and after discussions regarding the different reporting systems in States, and the advice and patient care received from pediatricians and public and private health clinics, Dr. Katz, speaking for the Immunization Practices Advisory Committee (ACIP), stated that he appreciates and understands DPT's concerns. He agreed that improvements should and must be made in the vaccine, in the reporting system of vaccine-related deaths, and in educating the public; he applauded the group for their work; and he suggested that they channel their efforts and leadership to areas applicable (e.g., American College of Pathology, FDA). He urged them to contact their representatives and senators to seek an augmented budget for CDC to carry out the types of surveillance and related activities necessary to improve the present system. Dr. Katz reviewed the function of the ACIP which is to provide advice and guidance regarding the appropriate application of antigens and related agents (e.g., vaccines, antisera, immune globulins) for effective disease control. The ACIP issues guidelines for administering a vaccine after it is licensed; FDA is responsible for licensing vaccines. He pointed out that ACIP does not have the mandate to educate coroners, medical professionals, parents, the States, and the general public; nor is ACIP charged to supervise the surveillance system--this, however, is provided by the Division of Immunization, Center for Prevention Services, CDC.

Dr. Hinman gave a summary of the CDC Monitoring System. The MSAEFI reporting system is voluntary. Dr. Hinman will consider adding questions to the MSAEFI form to obtain information that could help in evaluating whether "family history of severe reactions to DTP should be a contraindication to receipt of pertussis vaccine." Because of confidentiality, names are not listed on the MSAEFI form. Dr. Hinman felt that a better reporting systemn of vaccine-related deaths is desirable. The mission of educating coroners, medical professionals, and the States was discussed. Dr. Hinman will contact the American College of Physicians and the Academy of Pediatrics for advice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

August 28, 1986

TO : Members, Immunization Practices Advisory Committee (ACIP)
All Recipients of Minutes of ACIP

FROM : Executive Secretary, ACIP

SUBJECT : Minutes of ACIP Meeting on May 12-13, 1986

Please replace page 6 of the May 12-13 minutes with the attached page which contains a correction.

Thanks.

HTLV-III Infection and Live Virus Vaccines

Prior to the meeting, Committee members received for review a preliminary draft, "Immunization of Children Infected with Human T-Lymphotropic Virus Type-III/Lymphadenopathy-Associated Virus (HTLV-III/LAV)," developed by the Division of Immunization following consultations with seven experts chosen because of their experience with immunization and/or acquired immunodeficiency syndrome (AIDS). The consultants included Drs. James Chin and John Witte, State Epidemiologists in California and Florida, respectively; Dr. Polly Thomas, Director of the Immunization Program in New York City; Dr. Edward Mortimer, representing the ACIP; and Drs. James Oleske, Gwendolyn Scott, and Richard Stiehm, experts in pediatric AIDS and immunology. Dr. Walter Orenstein stated that the purpose of the draft is to summarize information and knowledge available at this time and to assist health care providers in the United States in developing policies for the immunization of children infected with HTLV-III/LAV--the virus that causes AIDS--and that periodic reassessment and revision will be required as more data become available. Between June 1981 and April 1986, 19,181 cases of AIDS (meeting the AIDS case definition) in the United States were reported to CDC; 274 of these cases were children under 13 years of age. Discussion was held considering the risks and benefits of immunizing children residing in the United States based on the risks of vaccine-preventable diseases and the prevalence of HTLV-III/LAV infection. Discussions also included whether individuals known to be infected with HTLV-III/LAV should be given live virus vaccines, whether screening was warranted, whether diagnostic serologic testing should be encouraged in situations where HTLV-III/LAV infection was clinically suspected, and on concerns and experiences with immunization of infected children. Dr. Katz asked the Committee to consider alternatives discussed and be prepared to resume discussion and to give comments of the preliminary draft the following day.

On day two, the Committee continued discussing the preliminary proposed recommendations for HTLV-III/LAV infections. Dr. Orenstein will incorporate suggested changes into another draft and circulate it to the Committee for review and comments.

Varicella-Zoster Update

Dr. Ken Brown, Merck Sharp and Dohme, gave a comparison of research/consistency lots of OKA/Merck VZV vaccine. Research and consistency lots differ only in the PFU/antigen content of bulks, influenced by dilution factor to achieve 4000 PFU/dose.

The Division of Immunization, CDC, prepared a preliminary draft statement on the use of varicella-zoster virus (VZV) vaccine, for both routine and post-exposure use. The draft was sent to Drs. Samuel Katz, Jeffrey Koplan, Anne Gershon, Philip Brunell, and Gerald Quinnan (FDA) for review and comments. Comments and suggestions will be incorporated into another draft which will be circulated to the Committee for review and comments. The draft covers use of VZV for normal healthy infants, children, adolescents, and adults as well as children and adolescents with acute lymphocytic leukemia (ALL). This vaccine may be the first herpesvirus vaccine to be licensed and the first live attenuated vaccine recommended for immunocompromised individuals.

HTLV-III Infection and Live Virus Vaccines Corrected

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Haemophilus b Polysaccharide Vaccine Update

Dr. Margaret Oxtoby, Division of Bacterial Diseases, CID, CDC, summarized information on the reported cases of Haemophilus influenza disease after vaccination. Reports of all such cases are solicited, even if the illness onset is less than 2 weeks after vaccination when the vaccine would not be expected to be protective. Further data are needed on the proportion of vaccine doses given in each age group and on the degree of underreporting before reliable estimates of efficacy based on these cases can be made.

Dr. Esber, FDA, summarized data on the reported adverse events following vaccination with the Haemophilus b polysaccharide vaccine.

Dr. David Smith, Praxis Biologics, presented data on a postmarketing surveillance study in a California health maintenance organization on vaccine adverse reactions and efficacy.

Rabies Vaccine Update

Dr. Daniel Fishbein, Division of Viral Diseases, CID, CDC, presented data on two new rabies products for use in humans--a rhesus diploid cell rabies vaccine (RDRV) and a syringe containing a single lyophilized dose of human diploid cell rabies vaccine (HDCV) reconstituted in situ for intradermal administration. He presented for discussion a revised supplementary draft, "Rabies Prevention: Supplementary Statement on Rhesus Diploid Cell Rabies Vaccine and the Pre-exposure Use of Human Diploid Cell Rabies Vaccine by the Intradermal Route." The data presented included interference by chloroquine phosphate with the antibody response of RDRV. He described data on rabies neutralizing antibody titers after vaccination with HDCV with various doses of vaccine and two routes of vaccination (intradermal and intramuscular). Dr. Katz asked the Committee to return any additional comments or suggestions on the draft statement within 2 weeks.

Other ACIP Business

Dr. Katz briefly reviewed a letter (dated April 10, 1986, from Dr. Koplan) summarizing steps CDC has taken, with the assistance of public and private health agencies, to promote adult immunizations.

Drs. Koplan and Hinman are consulting with Dr. Roy Widdus, Institute of Medicine, about the possibility of a meeting on poliomyelitis immunization in 1987. Suggestions are welcome for agenda items to be addressed.

Lederle has not signed an insurance contract for producing DTP vaccine. We should know within several weeks whether Lederle will participate beyond July.

The fall Committee meeting will be held October 6-7, 1986. Tentative agenda items include measles elimination, post-vaccination considerations for hepatitis B vaccine, HTLV-III/LAV infection and live virus vaccines, and varicella-zoster virus vaccine.

With the thanks of the Chairman, the meeting was adjourned at 12:30 p.m.

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

Samuel L. Katz 15 Aug 1986

Samuel L. Katz, M.D., Chairman Date