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

MINUTES OF MEETING

Immunization Practices Advisory Committee
February 21-22, 1989
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control, Atlanta, Georgia, on February 21-22, 1989. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT
Dr. Samuel L. Katz, Chairman
Dr. James D. Cherry
Dr. Jeffrey P. Davis
Dr. W. Paul Glezen
Dr. Caroline B. Hall
Dr. F. Marc La Force
Dr. H. Denman Scott
Dr. Mary E. Wilson

Ex Officio Members
Dr. John R. LaMontagne (NIH)
Dr. Carolyn Hardegree (FDA)

Liaison Representatives
Dr. Rudolph L. Ozene (NACI)
Dr. Edward A. Mortimer, Jr. (AMA)
Dr. Michael R. Peterson (DoD)
Dr. Stanley A. Plotkin (AAP)
Dr. William Schaffner, II (ACP)
Dr. Ronald C. Van Buren (AAFP)

Executive Secretary
Dr. Mary E. Guinan

NAVY ENVIRONMENTAL HEALTH CENTER
CDR David Trump

OFFICE OF THE SURGEON GENERAL, U.S. ARMY
Col. Ernest T. Takafuji

NATIONAL INSTITUTES OF HEALTH
Dr. George Curlin
Dr. David L. Klein

HHS STAFF PRESENT
FOOD AND DRUG ADMINISTRATION
Dr. Carl Frasch
Roland Levandowski

CENTERS FOR DISEASE CONTROL
Office of the Director
Mr. Kevin M. Malone

HHS STAFF PRESENT (continued)
CENTERS FOR DISEASE CONTROL
Center for Infectious Diseases
Dr. Miriam Alter
Dr. Claire Broome
Ms. Suzanne Gaventa
Dr. Steve Hadler
Dr. Maurice Harmon
Dr. Mark Kane
Dr. Alan Kendal
Dr. Olen Kew
Brian Mahy
Dr. Harold Margolis
Linda Moyer
Dr. Patricia Reichelderfer
Dr. Lawrence Schoenberger
Ms. Susan Stokes
Dr. Peg Tipple
Dr. Jay Wenger

Center for Prevention Services
Dr. Roger Bernier
Dr. Steve Cochi
Dr. Rosamond Dewart
Mr. Conrad P. Ferrara
Dr. Karen Farizo
Dr. Brad Hersh
Dr. Alan R. Hinman
Dr. Sonja S. Hutchins
Dr. Walter Orenstein
Mr. George Seastrom
Mr. Robert H. Snyder
Dr. Mary Ann Sprauer
Dr. Paul Stehr-Green
Mr. Don H. Stenhouse
Mr. Ron Teske
Dr. Walter Williams
Dr. Paul Zenker

NATIONAL VACCINE PROGRAM OFFICE
Dr. Alan Hinman
Dr. Yuth Nimit

Others Present

Dr. Vincent Ahonkhai
Dustin Berry
F. A. Capilupo
Dr. Pinya Cohen
Peter Culeman
Dr. Corry Dekker
Dr. Bruce Dull
Michael Favin
Dr. Robert Gerety
Dr. Lance Gordon
Dr. Jill Hackell
Cynsie Johnson
Frank McCarthy
Dr. Ellen McGuire
Dr. Patrick McVerry
Wayne Morges
Joseph Oren
Nancy Sabalusky
Ms. Karlyn Shedlowski
G. M. Slusaw
Dr. David Smith
Dr. Mason Stout
Dr. David West
Dr. Jo White

The meeting was opened at 8:30 a.m. on February 21 by Dr. Samuel L. Katz, Chairperson. Dr. Katz introduced Ms. Cheryl Counts, the new ACIP coordinator, replacing Mrs. Judy Parham, who has taken another position at CDC.

Hepatitis

Dr. Steve Hadler, Division of Viral Diseases (DVD), Center for Infectious Diseases (CID), Hepatitis Branch, briefly discussed the draft revision, "Recommendations for Protection Against Viral Hepatitis." The draft was distributed to ACIP members for comments by April 1. The plan is to discuss this document at the next ACIP meeting(s), and publish it as a supplement to MMWR this spring or early next fall.

Dr. Harold Margolis, Hepatitis Branch, DVD, CID, presented hepatitis B trends, noting that since the vaccine was introduced, reported cases have continued to increase (approximately 5%-7% a year). Disease acquired through parenteral drug abuse and heterosexual contact has increased the most in recent years. There are currently 300,000 hepatitis B infections per year. Medical costs for acute infections are estimated to total $500 million annually, including direct medical care and work loss. Current recommendations are to immunize those groups at high risk of infection. As this strategy does not appear to be decreasing disease incidence, discussion of other control strategies, such as universal vaccination of certain groups, needs to be initiated. A blueprint for expansion of HB immunization was recently sent to Congress in response to their solicitation of information on hepatitis B control programs. This plan outlines several components of universal immunization to be implemented in stages, and estimates program cost and impact on disease, as follows: (1) universal screening of pregnant women for HBsAg and vaccination of infants born to HBV carrier mothers (already recommended); (2) universal immunization of infants and/or adolescents and (3) increased programs for high risk group vaccination. Universal immunization of infants and adolescents would be the ideal strategy, because they can be accessed by prevention programs before high risk lifestyles are initiated; however, resources required for such programs are not available, and a consensus must be built among expert groups. Current public sector costs are $15-$18 million per year, but would reach as high as $250 million annually if all components were to be initiated. The plan as sent to Congress will be sent to all ACIP members.

Dr. Mark Kane, Hepatitis Branch, DVD, CID, discussed two recent surveys regarding the implementation of the ACIP recommendations for universal screening of pregnant women for HBsAg, as published in June 1988. Results of one survey show that 73% of obstetricians in private practice are aware of the new recommendations, with 59% now screening all pregnant women. Sixty-five percent had begun such screening after the new guidelines were published. The other survey was directed at obstetrics programs in hospitals which served the public sector (indigent women), and showed a similar high level of universal testing of pregnant women. Thus, the new recommendations seem to be accepted and are being adopted by both the public and private sectors.

Dr. Hadler discussed hepatitis prophylaxis for needlestick exposures and provided a handout that gives reasons to consider revising the recommendations of June 1985, which are complex. There are two proposals, with the main difference being whether to always test the source of exposure for HBsAg. The second is most like the HIV recommendations and favors testing all source patients (is also more expensive), while the first is less costly and only tests the source if the exposed person has not previously been vaccinated. These options will be further discussed in later meetings and recommendations incorporated in the new prevention statement.

Dr. David West, Merck Sharp and Dohme, discussed a proposal that is currently under review by FDA to reduce the dosage of recombinant hepatitis B vaccine to infants, children, and adolescents based on data from five clinical studies. Infants and children (up through 10 years of age) receiving 2.5 mcg and 5 mcg receive almost the same level of protection. Dr. Katz stated that ACIP's role is unclear, based on the fact that FDA is responsible for the package inserts that specify dosage. Dr. Katz will be in touch with Dr. Paul Parkman of FDA to convey ACIP support for reduced dosage recommendations and to see what can be done to expedite this matter.

Immunization Issues in Occupational Settings

Dr. Edward L. Baker, Deputy Director, National Institute for Occupational Safety and Health (NIOSH), discussed "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers," developed by NIOSH and CID recently. This document is in response to recently enacted legislation, Public Law 100-607. This document, which has been distributed to all ACIP members, provides guidance concerning methods to reduce the risk in the workplace of infection with HIV and HBV.

The Occupational Safety and Health Administration (OSHA) currently has recommendations for prevention of blood borne diseases in the workplace under review by OMB. These recommendations, if approved, will be used as an instruction manual by OSHA inspectors. The review process will take over a year. Notice will appear in the Federal Register if released by OMB. There will be a comment period of 6-9 months, hearings, and public meetings. NIOSH will mail copies of the Federal Register notice to ACIP members.

Implications of New Measles Recommendations

Dr. Orenstein, Director, Division of Immunization (IM), Center for Prevention Services (CPS), gave a review of measles recommendations published in the MMWR on January 13, 1989. Brad Hersh described three recent measles outbreaks (handout) in Missouri, North Carolina, and Texas (two outbreaks in Texas). There is much frustration with implementation of the recommendations. He discussed the cost of vaccine for revaccinations during outbreaks. There is not enough money to help with outbreak control, and costs are not predictable. Recommendations in priority order are (1) implementation of prior recommendations; (2) revaccination of 12-14 month olds in affected schools only; (3) revaccinate persons vaccinated prior to 1980 in affected

schools only; and (4) implement recommendations in affected and high-risk schools. Single antigen measles vaccine or measles-rubella vaccine should be used whenever possible to save money. ACIP should consider a routine 2 dose regimen at its next meeting.

Mumps

Dr. Paul Stehr-Green, IM, CPS, went over the proposed final draft of the revised mumps recommendations (mailed to ACIP members in advance) which represent an update of the 1982 recommendations. There are no major changes. The epidemiology section has been updated, and there are various wording changes to make this statement consistent with other current ACIP recommendations. After much discussion regarding such points as the 1956 cutoff date, references to specific points, length of school exclusion, and vaccine shipment and storage, the Committee decided more time was needed for comments. Dr. Katz asked members to return their comments on the proposed revision by April 1 to Dr. Stehr-Green.

National Vaccine Program and Vaccine Injury Compensation

Dr. Alan Hinman, Director, National Vaccine Program, stated that since the Vaccine Injury Compensation Program Office was established in HRSA, 90 petitions or claims have been received. Complete claims are reviewed by internal staff; those that don't clearly meet the guidelines are sent out to independent reviewers. The vast majority of claims are incomplete. Recommendations will be prepared for the U.S. Claims Court. No payments or final decisions have been made as yet. An Advisory Committee on Childhood Vaccine will have its first meeting in April or May of this year. A trust fund (which now has in excess of $100 million) has been established for compensation and funding for retroactive claims.

The National Vaccine Advisory Committee has held three meetings and has recommended full funding for the National Vaccine Program. Three members will be rotating off, and the office staff will be enlarged to include a deputy coordinator and a professional staff member. The Program is developing vaccine information pamphlets and establishing improved surveillance of adverse events. Reviews of package inserts are underway at FDA. A mission statement for the National Vaccine Advisory Committee and a National Vaccine Policy statement were distributed to ACIP members.

Influenza Vaccine Utilization and Coverage

Dr. Mary Ann Sprauer, IM, CPS, discussed surveillance systems to monitor immunization. The United States Immunization Survey, discontinued after 1985, assessed U.S. immunization status by telephone or home interview. The Biologics Surveillance System continues to evaluate trends in vaccine supply. The Behavioral Risk Factor Surveillance System, a CDC household survey, evaluated influenza vaccine coverage in 1987. The information for 1987 is encouraging, suggesting improved vaccine coverage over prior years.

National Coalition of Adult Immunization

Dr. Orenstein stated the National Coalition for Adult Immunization, an informal group of organizations and individuals with the common aim of improving the immunization status of adults through information and education, has made some progress. A statement of the purposes of this Coalition was distributed. Also attached was a list of of member organizations.

HCFA/HMO Status

Mr. Ron Teske, IM, CPS, presented information on cost-effectiveness of influenza vaccine under Medicare. He reported on a demonstration project with HCFA with funding of up to $25 million annually for 4 years. Nine projects were operational during November 1988, with nine intervention and comparison sites selected, and 79,000 doses of vaccine administered to a target population of 1,592,000.

Dr. Walter Williams, IM, CPS, stated that managed health care (including health maintenance organizations [HMOs]) is a growing industry. The industry recognizes that prevention reduces costs. He discussed a 3-year cooperative agreement with an industry trade association to improve adult immunization. This will include a demonstration project. To evaluate current policy and practices, a questionnaire was mailed to HMOs, with a 30% response rate. The results showed that less than one-half of the HMOs had written adult immunization policies, there was minimal promotion of vaccine use, and record/data systems are inadequate to track immunizations. There is a need to establish written adult immunization policies, more provider/patient awareness of immunization recommendations, appropriate record/data systems, and a cost-effective delivery system.

Information Materials

Mr. Robert Snyder, IM, CPS, showed samples of a kit called "Arm With the Facts" available from CDC to health organizations for their individual reproduction and distribution. The kit consists of a 79 slide set, artwork, text, a video cassette (including panel discussion), an audiocassette, and information pamphlets (including seven translations). All material is in the public domain. An Adult Immunization Slide Set is also available from CDC Still Picture Archives. This set includes 134 slides dealing with adult vaccine preventable diseases, missed opportunities, and a series of cartoon figures. It is intended to assist health programs in making presentations about adult immunization. Ordering information was made available.

Haemophilus Influenzae - Update

Dr. Jay Wenger, Division of Bacterial Diseases, (DBD), CID, discussed results of two vaccine efficacy trials in Finland and Alaska. The vaccine was effective in Finland and ineffective in Alaska. The cause of this difference is unclear.

Dr. Carl Frasch, FDA, reported on FDA experience with Hib disease following use of the Haemophilus b conjugate (diphtheria toxoid) vaccine, which was licensed one year ago for use in children 18 months - 5 years of age. Almost no polysaccharide vaccine is being distributed at present. Conjugate vaccine may be more effective than polysaccharide vaccine in this age group.

Dr. David Smith, Praxis, Dr. Vincent Ahonkhai, Merck Sharp and Dohme, and Dr. Patrick McVerry, Connaught, briefly presented information on their respective company's Haemophilus b conjugate vaccines.

Influenza - Update

Dr. Patricia Reichelderfer, DVD, CID, gave a world overview of influenza activity. Different strains are predominant in different countries. In Asia, China reported H1N1; Japan reported H1N1, with sporadic influenza B; Hong Kong reported influenza B; and Singapore reported all types. Europe reported mostly influenza B, with epidemic peaks in December. Canada reported AH1N1.

Ms. Suzanne Gaventa, DVD, CID, reported on U.S. data from a surveillance system. They receive weekly reports from 64 laboratories around the country. Eighty percent reported type B, 15% type AH1N1, 5% H3N2. By January 1, AH1N1 increased to 32%, B decreased to 64%, and AH3N2 remained about the same (4%). Deaths rose above the epidemic threshold from influenza and pneumonia for 2-3 weeks.

Dr. Maurice Harmon, DVD, CID, presented information on the properties of virus strains that are circulating and distributed data. Dr. Lawrence Schoenberger, DVD, CID, stated that very few cases of Reye's Syndrome have been reported.

Dr. Alan Kendal, DVD, CID, noted that there have been two confirmed cases of swine flu in the United States this year.

Dr. Kendal then discussed vaccine recommendations and vaccine production for next year. The present vaccine contains three components. The World Health Organization decided to drop B/Victoria and include B/Yamagata. He attended meetings in Geneva and Washington to decide which vaccine components to include in vaccine for next year. Publication of the ACIP statement on influenza control will be delayed in order to contain recommendations in two stages: (1) background, vaccines, and vaccination strategies (scheduled for publication in early May); and (2) summary of vaccination recommendations and antiviral recommendations (anticipated for publication in September because a new antiviral, rimantadine, may be approved by the FDA before the next influenza season). A draft on Part 1 was distributed in advance of the meeting to ACIP members.

Dr. Peg Tipple, DVD, CID, discussed the draft recommendations mailed to members and went over the proposed changes for foreign travelers, persons who should not be vaccinated, and strategies for implementing the recommendations. The draft recommendations for target groups include three options for high-risk groups. Additional comments on the draft are due by March 15.

Dr. Paul Glezen gave an overhead presentation and distributed material regarding a study conducted in Houston, Texas, on patients hospitalized with acute respiratory disease. Data were collected from discharge records. He proposed that influenza vaccination be recommended for:

(1) All persons 65 years of age or older.
(2) All high risk persons (persons with chronic illnesses).
(3) All health care personnel.
(4) All household contacts of high risk persons.
(5) All pregnant women who will be in the third trimester during respiratory disease season.

Dr. David Fedson presented information on the Shenandoah Study, conducted in 1983 to determine if hospital based influenza immunization is a useful strategy. The data were obtained from Medicare discharge information. Records indicated that only 21% to 23% of elderly persons discharged from hospitals receive influenza vaccine each year. It was determined that influenza immunization of discharged persons would have been less costly than the hospital care of patients admitted with influenza-associated illnesses. A review of organized programs for influenza and pneumococcal immunization showed that in hospital outpatient clinics, 40% to 60% were immunized and 78% were immunized as inpatients. In nursing homes, 10% to 90% were immunized with influenza vaccine. No information was available from practicing physicians. He also discussed vaccine distribution in the United States, Canada, and the United Kingdom.

Discussion on target groups followed and further revisions proposed. There was much discussion on recommendations for foreign travelers. The section on strategies for implementing recommendations has been expanded, and the recommendations have been lengthened by one page.

Followup to Polio Epidemic in Israel

Dr. Walter Orenstein, IM, CPS, presented slides of data from the polio outbreak in Israel. In the early 60s, trivalent vaccine was administered, with cases continuing to occur and vaccine failures. In 1982, a new routine schedule was initiated--3 doses of enhanced IPV in 2 of the 15 subdistricts of Israel. Coverage for IPV generally exceeded 90% by age 1. The other 13 subdistricts continued to use a 4 dose schedule of OPV. No supplemental OPV was given to recipients of IPV. The recent outbreak started July 31, 1988. Sixty percent of the cases were 15 years of age or older. Of the 15 cases, 9 patients had received 3 or more doses of trivalent OPV. The remainder had received monovalent Type 1, IPV, no vaccine, or had unknown status. There was high susceptibility against Type 1 in teenagers and young adolescents preceding the outbreak. Following the epidemic, Israel abandoned IPV and has gone back to oral polio vaccine, and is considering a combined schedule to take advantage of the properties of both IPV and OPV.

Dr. Olen Kew, DVD, CID, showed locations of wild type 1 poliovirus genotypes worldwide. His research showed that a new technique (PCR) can detect small amounts of wild type virus in water sewage samples that contain large quantities of vaccine strains.

Acellular Pertussis Vaccine in the USA

Dr. Roger Bernier, IM, CPS, discussed a Swedish trial where two acellular pertussis vaccines were tested for efficacy in an infant population. It was determined that the vaccines were safe and effective in preventing whooping cough. However, the Division of Drugs, National Board of Health and Welfare in Sweden, decided not to grant a license for the acellular vaccine because efficacy was not considered high enough to warrant licensing. At present, the United States has two major options to either license vaccines based on existing data or to collect additional data on safety and efficacy, which would involve further studies. Questions to be answered include where to do the study, choice of vaccine, study design, and funding. If further studies

are judged necessary, licensure will be delayed until the mid 1990s. Alternate ideas proposed are licensing for boosters only and licensing on an interim basis.

An article from The Lancet on "Comparing the Efficacy of Pertussis Vaccines" was distributed, along with a notice of Research and Development Sources Sought from NIAID to conduct a trial to compare efficacy of one or more new acellular vaccines with a conventional whole cell product in an infant population.

Current Status of Varicella Vaccine

Dr. Jo White, Merck Sharp and Dohme, presented information on a varicella vaccine trial Merck has been conducting since 1981, adding varicella to MR vaccine. They vaccinated 5,000 healthy children. The vaccine proved safe, effective, well tolerated. Licensure may be sometime this summer and will include adults.

Vaccinia and Vaccinia Immune Globulin

Ms. Susan Stokes, Host Factors, CID, updated the Committee on the status of smallpox vaccine. In August 1983, the Director of CDC approved the distribution of smallpox vaccine to at-risk laboratory workers. In November 1987 FDA and CDC agreed to release smallpox vaccine for use in clinical trials approved under an IND application. Currently two clinical trials are in progress. The Armed Services continue to vaccinate new recruits. Wyeth Laboratories stores all smallpox vaccine used by CDC and the Defense Department. As of November 1988, they have 170,883 vials in stock. This entire stock of vaccine is under contract to and owned by CDC.

Vaccinia Immune Globulin (VIG) is released to labs for testing, research, and for treatment purposes. The entire supply, 2,100 vials as of February 1, 1989, is owned by the Department of Defense and has an expiration date of June 1990. Hyland Laboratories (which produced all VIG in the past) has no VIG in stock.

Other ACIP Business

The dates for the next ACIP meeting will be changed from May 23-24 to May 10-11. A date for the September meeting will be decided soon, and members will be notified.

With the thanks of the Chairman, the meeting was adjourned at 12:50 p.m.

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

Samuel L. Katz 18 April 1989

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