## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

# CENTER FOR DISEASE CONTROL ATLANTA, GOERGIA

#### SUMMARY MINUTES OF MEETING

October 14-15, 1976

The Immunization Practices Advisory Committee met in Atlanta, Georgia, October 14-15, 1976.

## COMMITTEE MEMBERS PRESENT

- Dr. David J. Sencer, Chairman
- Dr. H. Bruce Dull, Executive Secretary
- Dr. E. Russell Alexander
- Dr. Elizabeth Barrett-Connor
- Dr. Lonnie S. Burnett
- Dr. William R. Elsea
- Dr. Edwin D. Kilbourne
- Dr. Thomas M. Vernon

## Ex Officio

Dr. Francis A. Ennis, Bureau of Biologics, FDA (For Dr. Harry Meyer, Jr.)

## Liaison

Dr. Martha Yow, American Academy of Pediatrics Dr. John Davies, Laboratory Centre for Disease Control, Canada (For Dr. John D. Abbatt)

## COMMITTEE MEMBER ABSENT

Dr. Reuel A. Stallones

#### OTHER PARTICIPANTS

Dr. James C. Hill, National Institute of Allergy and Infectious Diseases, NIH

Dr. Saul Krugman, New York University School of Medicine

Dr. John Robbins, Bureau of Biologics, FDA

## PRINCIPAL CDC STAFF PRESENT

Office of the Center Director:

Dr. William Foege

Office of Information:

Mr. Donald Berreth

Bureau of Epidemiology:

Dr. Philip Brachman

Dr. John Bryan

Dr. David Fraser

Dr. Michael Gregg

Dr. Barry Hafkin

Dr. Larry Schonberger

Dr. John Sullivan-Bolyai

Dr. Theodore Isai

Dr. Joel Ward

Dr. William Winkler

Bureau of Laboratories:

Dr. Walter Dowdle

Dr. Alan Kendal

Dr. Gary Noble

Bureau of State Services:

Mr. Windell Bradford

Dr. J. Lyle Conrad

Dr. Neal Halsey

Dr. Gregory Hayden

Mr. William O. Hosking

Mr. Harold Mauldin

Dr. J. Donald Millar

Dr. Walter Orenstein

Dr. John Witte

The meeting was called to order at 8:30 a.m. by the Chairman who thereafter relinquished the chair to the Executive Secretary for the remaining sessions. Dr. Alexander agreed to serve as secretary pro tem.

## Pneumococcal Polysaccharide Vaccine

Dr. John Robbins of the Bureau of Biologics (FDA) reviewed the long history of interest in pneumococcal vaccines, particularly referring to the high case fatality of pneumococcal pneumonia prior to antibiotic therapy. He noted that although there is currently felt to be as much pneumococcal disease now as there has always been, there are far fewer deaths due to effective therapy. However, some deaths do continue to occur. Dr. Robbins noted that it is generally accepted that about 20 of approximately 74 serotypes of the pneumococcus cause most of the current pneumococcal disease. In that capsular antibodies appear to be protective, chemical derivatives of the capsule have been tested for their antigenicity and protective capacity. Improved technology in their preparation has greatly enhanced their antigenicity for most age groups. It appears that the initial antibody response probably persists for life.

The pneumococcal polysaccharide vaccines which have been tested most extensively and may be licensed for use in several months are polyvalent products containing up to 15 different chemical antigens. They have been shown to reduce pneumococcal disease by approximately 80% or more in groups sufficiently prone to pneumococcal disease to make testing feasible (gold miners in South Africa, for example). Epidemiologic studies of the prevalence of pneumococcal diseases and their particular characteristics in various groups in the United States have been hampered by the relative uncommonness of pneumococcal disease in many groups and the unavailability of simplified serologic testing. Thus, the need for pneumococcal vaccine of varying kinds and assessment of their usefulness have and presumably will have to continue to depend on microbiological and clinical observations.

Dr. David Fraser, CDC, joined with Dr. Robbins in discussing some of the available field trial data. In general it was felt that the inherent difficulties in diagnosis and case definition have hampered trials. This was felt to be particularly so in studies where seroconversion played an important part in case definition, especially studies where seroconversion was not always accompanied by clinically demonstrable pneumonia.

The Committee's discussion focused on population groups and possible geographic areas where pneumococcal vaccines could be sufficiently useful to recommend their regular use. The Committee found it difficult to specify need precisely enough with available epidemiologic and clinical information to designate high-risk or other populations likely to profit from the systematic use of pneumococcal vaccines. The topic will be considered until the next ACIP meeting at which time it will again be discussed.

## Diphtheria Antitoxin

Based on requests to CDC for guidance on the use of diphtheria antitoxin in managing certain household contacts of diphtheria cases, the Committee considered alternative proposals. Most important in this regard is management of persons who cannot be kept under sufficient surveillance to detect the onset of signs and symptoms. A draft recommendation was developed for consideration as an inclusion in the DTP Statement when it is next revised.

Basically, the recommendation balances the benefits and risks of diphtheria antitoxin and antibiotics under varying conditions of exposure and follow—up. Committee comments on the draft were requested within two to three weeks.

## Influenza

Dr. Donald Millar reviewed the status of the National Influenza Immunization Program, noting first that surveillance of influenza is clearly the most intensive ever organized in this country. Of some 8,000 suspect influenza case specimens processed in 76 laboratories between May 22, 1976, and October 3, 1976, 9 strains of A/Victoria and 8 of B/Hong Kong have been identified. No A/New Jersey (swine influenza virus) has been recovered.

It was estimated that nearly 900,000 vaccinations have been given in the first few days of the national campaign. Dr. Millar reviewed for the Committee four problems which have confronted the program: (1) liability for inherent risk, (2) ready availability of vaccine, (3) the differences between split-virus and whole-virus vaccines and their relative applicability to varying age groups and thus the matters of vaccine recommendations for children and adolescents, and (4) the temporal association of vaccination and fatality. With regard to the latter point, Dr. Millar described the 14 deaths reported, all between the ages of 53 and 86. Investigations have been unable to determine explanations other than sheer coincidence with having received vaccine.

Dr. Noble reviewed for the Committee the data on which the Committee on Infectious Diseases of the American Academy of Pediatrics had in early September 1976 derived recommendations for immunizing high-risk children. The acceptability of split-virus vaccines with respect to minimal side effects and their ability in a two-dose schedule to produce a high level of seroconversions with good antibody responses were clearly evident. Dr. Noble noted that at an Influenza Workshop to be held on October 22, 1976, these and additional data would be reviewed, essentially a conclusion of reports on the field trials conducted this year.

## Polio Vaccines

The Committee reviewed the existing draft recommendation on polio vaccines which describes both the inactivated and the live virus vaccines and attempts to put them into perspective with regard to their potential applicability in the United States. Editorial suggestions and minor content changes were recommended for a next draft.

## Measles, Mumps, and Rubella Vaccines

Dr. Saul Krugman, consultant to the Committee, presented results of several recent studies on seroconversion rates to live, further attenuated measles vaccine given at varying ages encompassing 12-15 months. It was evident from tabular material provided to

the Committee that seroconversion rates of approximately 95% occurred when the vaccine was administered to children at 13-15 months of age but that in some studies this level fell to approximately 80% when the vaccine was given at only 12 months. The Committee suggested that its current measles recommendation be changed to show a preference for delaying measles vaccination enough to achieve the highest seroconversion rate and recommend that children have at least passed their 12-month birthday before being immunized. The current draft recommendation on measles vaccine was recommended to include this change and also to incorporate material presented to the Committee on the temporal association of SSPE with measles vaccine and on a more current appraisal of the reported complications of measles and of measles vaccines.

Having insufficient time to review in detail the mumps and rubella statements, the Committee requested that new drafts be mailed for review and consideration. The changes in these statements will be primarily updating factual material and an increased emphasis on the rubella immunization of susceptible prepubertal girls. The Committee was agreeable to the alternative approach of correspondence on the statements rather than personal discussion.

## Polio Vaccine Consent Form

The Committee was shown a draft consent form to accompany the Federally-purchased oral polio vaccine. The form developed by CDC staff attempts to portray the benefits and risks of oral polio vaccine in a way sufficiently complete to permit the recipients or their parents or guardians to make an informed choice. The Committee generally believed the draft form to be too long and recommended that a shorter version be developed which would achieve the informational objective of the consentobtaining process.

With the thanks of the Acting Chairman, the meeting was adjourned at approximately 4:00 p.m.

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

Acting Chairman

Date