DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA

SUMMARY MINUTES OF MEETING

May 14-15, 1975

The Immunization Practices Advisory Committee met in Atlanta, Georgia, May 14-15, 1975.

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. E. Charlton Prather
Dr. Eleanor G. Shore
Dr. Reuel Stallones

Ex Officio

Dr. Harry Meyer, Bureau of Biologics, FDA, DHEW

Liaison (American Academy of Pediatrics)

Dr. Samuel Katz

STAFF PRESENT

Bureau of Epidemiology:	Dr. John Bennett Dr. Philip Brachman Dr. Lawrence Corey Dr. Michael Gregg Dr. Charles H. Hoke, Jr. Dr. Jay Jacobson
Bureau of Laboratories:	Dr. Walter Dowdle Dr. Gary Noble Dr. Roslyn Q. Robinson
Bureau of State Services:	Mr. Harold Mauldin Dr. J. Donald Millar (Acting Chairman for portion of meeting) Dr. John Witte

The meeting was called to order at 8:30 a.m. by the Executive Secretary acting for the Committee's regular Chairman, Dr. David J. Sencer, Director, Center for Disease Control, who was temporarily delayed in assuming the chair. Two new members of the Committee were introduced:

Dr. E. Russell Alexander
Professor and Chairman
Department of Epidemiology and
International Health
University of Washington
School of Public Health
Seattle, Washington 98195

Dr. Reuel A. Stallones
Dean
School of Public Health
University of Texas
Houston, Texas 77025

The Acting Chairman discussed the proposed agenda and described the intent of the spring meeting as formulation of recommendations on influenza and meningococcal disease, particularly the application of available vaccines to prevention and control. Also, the Committee would be asked to continue its review of revised recommendations on Immune Serum Globulin for Protection Against Viral Hepatitis and on Poliomyelitis Vaccine and to review implications of Reyes v. Wyeth and related litigation on the conduct of public health immunization programs.

Influenza

As is traditional at its spring meeting, the Committee reviewed surveillance of influenza in the United States and internationally. It was shown that during the winter season in 1974-75, considerable Type A influenza was observed in the United States and in many parts of the world. Influenza activity in the United States was due almost entirely to A/Port Chalmers/1/73. The first confirmed outbreaks occurred in Hawaii in early November. In the continental United States, the first influenza was reported in Georgia, Tennessee, and Florida in early December. By late December, influenza was confirmed in most of the South Atlantic and East South Central states. Subsequently, influenza spread west and northeast. Reports of outbreaks and of influenza virus isolates decreased markedly by March.

Pneumonia and influenza mortality was observed in 121 United States cities having a total population of 70 million people from the second through the tenth week of 1975. A total of 1,600 excess deaths were reported in these cities during the epidemic period. Extrapolating to the whole U. S. population, this could represent up to 4,800 excess deaths due to pneumonia and influenza.

Influenza virus isolations characterizing outbreaks of disease in the United States indicated the presence of Type A viruses from mid-November 1974 to early March 1975. No outbreaks of influenza due to Type B viruses were reported. Strains of Type A viruses recovered in the United States generally showed consistency and relationship of prevalent strains to A/Port Chalmers/1/73. It was of particular interest, however, that, internationally, a distinctive Type A strain, A/Scotland/840/74, with apparent epidemic potentiality, appeared in several areas. The presence of this strain in connection with outbreaks of disease was of importance in leading to a reformulation of influenza vaccine for 1975-76 in the United States. Consequently, the Bureau of Biologics recommended that the A component of influenza vaccine for the coming season be comprised of one-half A/Scotland and one-half A/Port Chalmers.

Vaccine Reactions

Information from various sources, much derived in retrospect, suggested a sometimes heightened occurrence of local and systemic reactions to currently available influenza vaccines. However, the lack of strict comparability among products and details of the observations of reactions made accurate evaluation impossible. A few individual studies showed the occurrence of relatively frequent but generally mild side effects while others, employing somewhat similar products, had markedly dissimilar results. Limited testing of vaccines in infants and young children indicated that febrile responses were relatively common in this age group and that in some few instances, febrile seizures resulted. This latter observation prompted the Bureau of Biologics to advise manufacturers that the package literature for 1975-76 vaccines should call attention to this possible adverse effect.

In general, the Committee concluded that up to 20% of adult recipients of influenza vaccine might experience some mild systemic effects and local reactions such as erythema and tenderness at the injection site. The Committee urged that the statement on influenza vaccine for 1975-76 call attention more pointedly to such reactions, indicating the variation in expectation, but the relative likelihood that some vaccinees would experience local and perhaps systemic reactions.

Live Influenza Virus Vaccine

Dr. Noble described data from an investigation into the effectiveness of live, attenuated influenza vaccine used in young adults. In brief summary, it was found that in a comparison trial between inactivated vaccine and a live product, the former induced a higher proportion of antibodies in recipients and a higher average antibody titer than did the live, attenuated antigen. During an epidemic of Type A influenza, it was further observed that the inactivated vaccine was better able to reduce symptomatic illness than was the live vaccine.

Meningococcal Disease and Vaccine

Continuing its discussions from earlier meetings, the Committee reviewed surveillance data on meningococcal disease in the United States and internationally. There was considerable debate as to possible definition of epidemic meningococcal disease among civilians which might be used as a basis for recommending meningococcal vaccine. It was agreed that the possible use of vaccine in epidemic control would need to be an individualized judgment weighing factors such as the antibiotic sensitivity of involved strains, the usually limited nature of meningococcal meningitis outbreaks in the United States, the environment in which cases were occurring, etc. The Committee saw merit in developing a brief, descriptive statement on the available meningococcal vaccines and a perspective on their potential use in epidemic control. The group did not see justification for rapid liberalization of meningococcal vaccine distribution or general availability. Although data on duration of protection, effectiveness in infants and small children, and other parameters describing vaccine effectiveness could eventually lead to a more generalized recommendation for use, current data on the meningococcal polysaccharide vaccines suggest that their civilian use should be limited to selected conditions.

Poliomyelitis Case Review

Between 1969 and 1974, 114 cases of poliomyelitis were reported in the United States. In April 1975, an expert working group was assembled at CDC to review the cases, primarily to consider the currently-used criteria of clinical and laboratory diagnosis, the adequacy of surveillance, the associations of cases with vaccination or contact with vaccine recipients, and, in general, the categorization of vaccine-associated disability. The group's report to the Director, CDC, not yet available, is expected to reaffirm the bases of polio surveillance and the general designations of vaccine-associated paralysis. It was reported that the working group's review differentiated cases with infection occurring outside the United States and those in immune-deficient individuals. The group recommended that these latter cases be individualized among those considered to be vaccine-associated. It also suggested that the laboratory characterization of strains attempt to differentiate vaccine-like and non-vaccine-like strains as a reasonable basis for evaluating the potential role of vaccine viruses in vaccine-associated disability.

Report on Reyes v. Wyeth, Warnings, Information, Etc.

The Committee has regularly had considerable interest in the impact which litigation of vaccine-associated disability is having or may have on the conduct of immunization programs in public health practice. At

the present time, the opinion in Reyes v. Wyeth, one calling for response by manufacturers to reduce their liability for disability through warnings, insurance, physician administration of vaccines, etc., is receiving great attention by the producers prior to sale of vaccines during the coming year. How the private physicians and the public health practitioners will be affected by these decisions remains to be seen.

Prepublication Reviews

1. Poliomyelitis Vaccine

Based on its earlier discussion in the morning of poliomyelitis benefits and risks, the Committee reaffirmed its support of the current draft of the poliomyelitis vaccine recommendation soon to be published along with other Committee statements.

2. ISG and Hepatitis

The Committee recommended a somewhat more liberalized use of currently available ISG for persons exposed on single occasions to substances containing hepatitis-B. The Committee concluded that, in some instances, existing data support the effectiveness of ISG used under these conditions. Data from studies of hepatitis-B hyperimmune globulins used for prevention of hepatitis following more extensive hepatitis-B exposures may help to clarify the role of passive immunization with respect to hepatitis-B prevention and control.

3. Other Drafts

Preliminary draft statements on influenza vaccine and meningococcal vaccine were considered. Editorial and other changes were recommended prior to publication. The meningococcal vaccine statement in particular will be extensively modified and circulated to Committee members for additional comments.

Other Business

The Committee selected Monday-Tuesday, October 6-7, 1975, for its regular fall meeting. A tentative agenda item for a portion of that session was recommended to be hepatitis-B carriers among health professionals.

The meeting adjourned at 3:00, May 15, 1975.

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

for H Brandwein 6/4/75
Chairman Date