DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA

SUMMARY MINUTES OF MEETING

January 14, 1977

The Immunization Practices Advisory Committee met in Atlanta, Georgia, January 14, 1977. Those in attendance are listed below:

COMMITTEE MEMBERS

Dr. David Sencer, Chairman
Dr. Michael Gregg, Secretary Pro Tem

Dr. Elizabeth Barrett-Connor
Dr. William Elsea
Dr. Edwin Kilbourne
Dr. Reuel Stallones
Dr. Thomas Vernon

Ex-officio Members

Dr. William Jordan
National Institute of Allergy
and Infectious Diseases, NIH

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

Liaison Member

Dr. John Abbatt
Laboratory Centre for Disease
Control, Canada

CONSULTANTS

Lt. Col. John Cutting
U. S. Army

Dr. John Fox
University of Washington

Dr. Saul Krugman
N.Y.U. Medical Center

Dr. Alexander Langmuir
Harvard Medical School

DEPT. OF HEALTH, EDUCATION, AND WELFARE

Office of Asst. Secretary for Health (ASH)

Dr. Delano Meriwether
Special Assistant to ASH

Office of General Counsel

Mr. Charles Gozonsky
Legal Advisor

National Institutes of Health

Dr. Richard M. Krause, Director
National Institute of Allergy
and Infectious Diseases

Dr. David L. Madden, Deputy Chief
Infectious Diseases Branch
National Institute of Neurological
and Communicative Disorders
and Stroke

Center for Disease Control

Office of Center Director

Dr. William Foege

Office of Information

Mr. Robert Alden
Mr. Donald Berreth
Ms. Betty Hooper
Ms. Katherine Lord
Mr. Stafford Smith

Office of Program Planning/Evaluation

Mr. Andrew Sumner

Bureau of Epidemiology

Dr. Philip Brachman
Mr. Dennis Bregman
Dr. John Bryan
Dr. J. Lyle Conrad
Dr. Barry Hafkin
Dr. Neal Halsey
Dr. Gregory Hayden
Dr. Michael Hattwick
Dr. Richard A. Kaslow
Dr. Richard Keenlyside
Mr. Leo Morris
Dr. Richard O'Brien
Dr. Walter Orenstein
Ms. Frances Porcher
Dr. Lawrence Schonberger
Dr. John Sullivan-Bolyai
Dr. Ronald Zweighaft

Bureau of Health Education

Mr. Bill Griggs

Bureau of Laboratories

Dr. Walter Dowdle
Mr. Harold Kaye
Dr. Alan Kendal

Bureau of Smallpox Eradication

Dr. J. M. Lane

Bureau of State Services

Mr. Jack Jones
Mr. Mike Kerr
Mr. Harold Mauldin
Dr. J. Donald Millar
Mr. Max Pesses
Mr. Jerry Spyke
Dr. John Witte

OBSERVERS

Frank Brandon, Parke-Davis & Co.
Victor Cohn, Washington Post
Bebe Emerman, WSB-TV
Craig R. Hume, Atlanta Constitution
Bob Rountree, WBIE/WCOB
B. A. Rubin, Wyeth Laboratories
H. Schmeck, New York Times
Charles Seabrook, Atlanta Journal
Jack Stillman, Associated Press
Charles S. Taylor, United Press Int'l

The meeting was called to order at 1:00 p.m. by the Chairman, who stated that the audio portion of the meeting was being transmitted to Classroom 1, CDC, where the "overflow" audience was being accommodated. Dr. Gregg agreed to serve as Secretary Pro Tem.

Dr. Sencer opened the meeting by stating that the purpose of the meeting was to review all available data on influenza vaccination and the Guillain-Barre syndrome (GBS) that had been gathered since the ACIP meeting on December 29, 1976, and to make recommendations regarding the U.S. influenza immunization program. The meeting followed the prepared agenda.

Dr. Millar reported that somewhat over 42 million doses of vaccine have been given and that the moratorium on vaccination has been maintained adequately. State health departments are requesting clarification of informed consent for private physicians who wish to vaccinate their patients. CDC is trying to develop materials to clarify the role of the private physician and is working on a consent form that will incorporate a statement on the risk of GBS. CDC is further defining where the remaining stores of vaccine are. Dr. Millar estimated that there are approximately 60 million distributed but as yet unused doses of swine influenza vaccines in the United States.

Dr. Richard O'Brien (for Dr. Hattwick) summarized the status of influenza in the United States. Generally the activity has been minimal; most of the recent isolates have been type B. In Ixonia, Wisconsin, 2 contacts of a documented case of A/New Jersey influenza have shown seroconversions to the A/New Jersey virus. Neither had contact with pigs nor had received A/New Jersey vaccine. Both had mild illness. To date 3 isolates of A/Victoria and 3 isolates of A/New Jersey have been identified in the U.S.. Worldwide, the predominant influenza isolates have been type B. Dr. Alan Kendal briefly reviewed an analysis of the recent B isolates, indicating there was no significant drift in hemagglutination (HA) antigen from earlier B/Hong Kong strains.

Dr. Lawrence Schonberger reviewed data on Guillain-Barre syndrome cases in the United States. As of January 12, 1977, 582 cases have been reported to CDC: 292 received A/New Jersey vaccine prior to onset of disease, 265 were among unvaccinated persons. Five cases had received influenza B vaccine; for 13, the influenza vaccination status is unknown. In 21 states where reasonably complete information is available on cases and vaccine distribution, overall attack rate by cases per million person months of risk is 6.6--a relative risk of 11.0. Using 4 weeks or less as the period of probable risk of developing GBS, the attack rate for all cases is 8.3--a relative risk of 14.4. This computes to 1 case of GBS for every 143,000 doses of vaccine administered, although the confidence limits range from approximately 100,000 to 200,000.

Dr. John Sullivan-Bolyai briefly summarized a comparison of vaccinated and unvaccinated cases of GBS by clinical status. Among the 582 cases, detailed clinical information is available on 164. It shows that there is no statistically significant difference between vaccinated and unvaccinated groups in all clinical parameters measured; however, there is a statistically significant difference between the two groups with respect to a history of acute illness in the past 4 weeks. The non-vaccinated group of GBS patients show a statistically higher incidence of preceding acute illness in the past 4 weeks as compared to the vaccinated group. Dr. Richard Keenlyside reported that of 21 deaths due to GBS reported to CDC from October 1, 1976, to January 12, 1977, 18 cases were seen by neurologists. Most of the deaths were attributable to respiratory failure.

Lt. Col. John Cutting, representing the Army, reported briefly that since October 1, 1976, the military had given more than 1.5 million doses of A/New Jersey vaccine to military personnel and 861,000 doses to non-military personnel. Among all three services, 26 cases of GBS have been identified; 16 of the patients received the A/New Jersey vaccine. Dr. Cutting reviewed the cumulative experience of the Army regarding Guillain-Barre cases 1971-75, and, although case ascertainment at this time may not reflect the total number of cases occurring within Army personnel, the Army's recent experience with GBS does not appear to indicate an unusual number of cases.

Dr. Barry Hafkin summarized laboratory efforts of the National Institutes of Health and CDC to date on GBS, indicating that the NIH and its cooperating laboratories have identified 34 patients for study. CDC has identified 18

acutely ill patients, from 6 of whom blood samples have already been collected. Dr. John Fox emphasized the need to uncover the mechanisms of GBS if at all possible and encouraged collection of appropriate specimens.

Dr. Neal Halsey gave a brief review of the literature regarding GBS reported to follow administration of vaccines other than influenza. He emphasized that cases were reported voluntarily and that total numbers of vaccine recipients were unknown, making conclusions very difficult to interpret. Furthermore he pointed out that there were inconsistencies in the neurological diagnosis and that the relationships between the clinical events and vaccination were only temporal. Notwithstanding these limitations in interpretation, a variety of neurological conditions have been reported infrequently following most standard available vaccines, and GBS did not appear to be particularly common or noteworthy. Mr. Leo Morris reviewed poliomyelitis data collected by CDC 1958-62 regarding paralytic disease following use of the inactivated polio vaccine (IPV). During these years 249 million doses of IPV were given and 20,334 cases of polio were reported. Among these, 794 cases of poliomyelitis reportedly occurred less than 30 days following receipt of IPV. Five hundred and fifty of these cases had paralysis, 67 of whom had no residual paralysis at 60 days. One of the cases had a diagnosis of transverse myelitis, and one a diagnosis of Landry's paralysis. It was stressed that because local and State health departments as a general rule screened poliomyelitis cases carefully prior to reporting them to CDC, GBS cases would be rarely reported to CDC.

Dr. Saul Krugman, NYU, briefly reported on 49 cases of post-vaccination encephalitis following the 1947 smallpox mass immunization program in New York City. He emphasized the need to adopt rigid criteria for defining the Guillain-Barre syndrome.

Conclusions

It was generally concluded that, although more data will be collected and may result in some changes in actual risk, there appears to be a clear association between influenza immunization in 1976 and the Guillain-Barre syndrome. The extent of the risk from influenza vaccine can be at least generally defined and should be incorporated in the informed consent statement. It was also felt that because the influenza season in the United States in 1976-77 has been remarkably quiet and the influenza surveillance system is sensitive, there probably would be sufficient time to reinstitute vaccination for the remaining population should an A/New Jersey strain emerge.

The recommendation, therefore, was made to lift the moratorium on all influenza vaccines and to reinstitute vaccinating the high-risk groups. Private physicians and health departments, however, could offer influenza vaccine to the rest of the population if they chose. However, in the event of a significant amount of A/New Jersey influenza activity in the United States, the Public Health Service should recommend immediate resumption of vaccination with the monovalent A/New Jersey vaccine of all unprotected groups.

With the thanks of the Chairman to all participants for their instructive participation, the meeting was adjourned at 4:45 p.m.

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

Dan Reicen FEB 1 1977

Chairman Date