

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA

SUMMARY MINUTES OF MEETING

December 29, 1976

The Immunization Practices Advisory Committee met in Atlanta, Georgia, December 29, 1976. Those in attendance are listed below:

COMMITTEE MEMBERS

DEPT. OF HEALTH, EDUCATION, AND WELFARE

Dr. David Sencer, Chairman
Dr. Bruce Dull, Executive Secretary

Office of Asst. Secretary for Health (ASH)

Dr. Delano Meriwether
Special Assistant to ASH

Dr. Russell Alexander
Dr. William Elsea
Dr. Edwin Kilbourne
Dr. Reuel Stallones
Dr. Thomas Vernon

Office of General Counsel

Mr. Charles Gozonsky
Legal Advisor

Ex-officio Members

National Institutes of Health

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

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

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

Dr. Dale McFarlin, Chief
Neuro-Immunology Branch, National
Institute of Neurological and
Communicative Disorders and
Stroke

Liaison Members

Dr. A. G. Jessamine (for Dr. Abbatt)
Laboratory Centre for Disease Control
Canada

Center for Disease Control

Dr. Samuel Katz (for Dr. Martha Yow)
American Academy of Pediatrics

Office of Center Director

Dr. William Foegen

CONSULTANTS

Office of Information

Dr. John Fox, Univ. of Washington
Dr. Saul Krugman, N.Y.U. Medical Center
Dr. Alexander Langmuir, Harvard Med. School
Dr. Ronald Lesser, Neurological Inst., N.Y.
Col. Philip Russell, Walter Reed Hospital

Mr. Donald Berreth
Mr. Stafford Smith

Office of Program Planning & Evaluation

Dr. George Hardy
Mr. Paul Stange
Mr. Andrew Sumner

Bureau of Epidemiology

Dr. Philip Brachman
Mr. Dennis Bregman
Dr. John Bryan
Dr. Richard Dixon
Dr. Philip Graitcer
Dr. Michael Gregg
Dr. Michael Hattwick
Dr. R. A. Kaslow
Dr. Richard Keenlyside
Dr. Lawrence Schonberger
Dr. John Sullivan-Bolyai
Dr. Ronald Zweighaft

Bureau of Laboratories

Dr. Walter Dowdle
Dr. Jared Gardner
Mr. Harold Kaye
Dr. Alan Kendal
Dr. Gary Noble

Bureau of State Services

Mr. Windell Bradford
Mr. Larry Brown
Dr. Lyle Conrad
Dr. Neal Halsey
Dr. Gregory Hayden
Mr. William Hosking
Ms. Debbie Hutto
Mr. Mike Kerr
Mr. Harold Mauldin
Mr. Jerry Spyke
Mr. Ron Teske

OBSERVERS

Media

Ms. Roz Abrams (WSB Radio)
Mr. Bahr (CBS)
Mr. Ernie Bjorkman (WSB-TV)
Mr. Phil Boffey (Science Magazine)
Mr. Victor Cohn (Washington Post)
Mr. Bernard Goldberg (CBS)
Mr. William Hines (Chicago Sun Times)
Mr. Craig R. Hume (Atlanta Constitution)
Mr. Don Harris (NBC)
Ms. Diane Kennedy (WQXI)
Mr. John Patrick (WAGA-TV)
Ms. Judith Randal (New York Daily News)
Mr. Bob Rountree (WBIE/WCOB/Mutual)
Mr. Charles Seabrook (Atlanta Journal)
Mr. Jack Stillman (Associated Press)
Mr. Charles Taylor (United Press International)
Mr. Joe Washington (WXIA-TV)
Mr. Bill Wordham (ABC)
Mr. Don York (WZGC)

Others

Mr. Frank Brandon (Parke Davis & Co.)
Ms. Leslie Graitcer (Health educator)
Dr. Peter Dowling (Veterans Administration)
Mr. Don Metzgar (Merrell-National Labs)
Mr. Ronald Phesser (Columbia Presbyterian Medical Center)
Mr. Herbert Segal (Walter Reed Army Institute of Research)
Mr. Charles Suttle (Wyeth Laboratories)

The meeting was called to order at 1:00 p.m. by the Chairman, Dr. David Sencer, Director, Center for Disease Control, who welcomed those present and noted that the audio portion of the meeting was being transmitted to Classroom 1, CDC, where the "overflow" audience was being accommodated. Time was then allowed for the press representatives to make photographs of the Committee and other meeting attendees.

Dr. Sencer, in his introductory comments, indicated that the purpose of the meeting was to review all available data on the Guillain-Barre syndrome within the context of the National Influenza Immunization Program (NIIP) and the status of influenza in the United States and the rest of the world. The meeting followed the prepared agenda.

Dr. Millar briefly reviewed concepts and conduct of the NIIP indicating the extensive field testing of vaccines to be used and the intensive surveillance network developed to track the course of the program and any possibly associated adverse events. He stated that at the time the moratorium on vaccinations was called in mid-December, approximately 41.5 million doses of vaccine had been given, reflecting a United States median of 30% coverage. The range of coverage among States was from less than 10% to more than 75%.

Dr. Dowdle, in demonstrating the very limited amount of influenza occurring in the United States and elsewhere in the world, presented data indicating that from the many thousands of specimens submitted to WHO laboratories for virus isolation and paired sera for serologic diagnosis, only a few strains of A/Victoria and B/Hong Kong have been identified. No outbreaks have been reported, and only sporadic cases have come to attention. He described the 3 swine influenza cases identified in the United States, indicating that in 2 instances there was swine contact which may have been the source of infection. (In regard to swine influenza, it was pointed out that there have been a number of swine influenza viruses isolated from pigs in the Middle West during the last months, a not uncommon finding.)

Dr. Gregg in his review of mortality characteristics of influenza showed that during influenza epidemics identified 1911-76, excess mortality was most commonly first observed in December or January.

Dr. Hattwick, in describing NIIP surveillance of adverse effects possibly related to influenza immunization in 1976, presented a tabulation of 160 fatalities occurring within 48 hours of vaccination. Investigation provided no evidence that the vaccine contributed to the deaths.

Dr. Schonberger reviewed all available data on the Guillain-Barre syndrome and its possible association with influenza vaccination. As of the date of the meeting, 496 cases have been identified both through spontaneous reports and by more intensive surveys carried out in approximately 10 States. Of them, 246 had received vaccine, 234 had not; and in 16, vaccination history was not known. Nineteen of the cases ended in death, a case fatality of approximately 4%. Eleven of the deaths were in vaccinated persons, 8 in non-vaccinated.

Meeting participants emphasized the great importance in the analysis of Guillain-Barre and influenza vaccine for uniformity of diagnosis and comparability of the intensity and methodology of case ascertainment in vaccinated and unvaccinated patients. It was therefore urged that, as additional cases are identified, comparable clinical and laboratory findings be carefully interpreted.

In presenting various analyses of the cases, Dr. Schonberger pointed out several findings: (1) an approximately equal number of males and females were affected; (2) ages of patients ranged between 5 and 90 years, most occurring in the 30 to 60 year age range; (3) no single vaccine or

manufacturer was primarily involved; and (4) no significant geographic distribution was apparent. Although the relative risk of Guillain-Barre syndrome was generally 2 to 10 times greater among the vaccinated, the data were judged to be quite preliminary with the denominators particularly questionable. Thus emphasis was placed on 3 epidemiologic distinctions between the groups: (1) the shape of the curve of Guillain-Barre cases with respect to time, indicating an unseasonal frequency; (2) an age distribution among vaccinated cases unlike that among the unvaccinated; and (3) a clustering of cases approximately 2-3 weeks after vaccination.

There was considerable discussion of the importance of careful investigation of all cases. It was pointed out that the etiology and pathophysiology of Guillain-Barre may be far better understood as a result of the current experience. Full advantage should therefore be taken of the cases which are identified and available for detailed study. Representatives of the National Institutes of Health described their current activities and plans with respect to Guillain-Barre research investigations. They encouraged prompt communications among research and clinical centers with interest in pursuing specific studies.

Conclusions

It was generally concluded that although the data are still preliminary and incomplete, there is a clear association between influenza immunization in 1976 and Guillain-Barre. The actual risk cannot be stated at the present time, and more data must be assembled to make an estimate. The group urged continuation of the moratorium on the NIIP and of intensive efforts to ascertain cases. This process was felt to require a minimum of two additional weeks, if not more.

Some few persons in attendance believed that persons at high risk of serious or fatal consequences of influenza should have access to the bivalent swine influenza vaccine if so recommended by their physicians, even though a general moratorium is to be continued. Others believed that if influenza, either of A/Victoria or A/New Jersey (swine influenza virus), should become prevalent, there would be sufficient time to reinstitute vaccination for high-risk persons. In this regard, since there is only minimal influenza activity at present, notice of the need to reactivate vaccination activities should be adequate for prompt reinitiation of the program.

With regard to which influenza vaccines should be covered by the continuing moratorium, the original directive included influenza B vaccine and should not be changed at this time.

The Chairman in summing up the sense of the meeting made 3 final comments on resulting recommendations: (1) continue the moratorium; (2) rapidly get the best possible data on numbers and characteristics of the Guillain-Barre cases, and (3) allow physicians to have access to bivalent swine influenza vaccine for their high-risk patients, with the understanding

that formal informed consent procedures would be used and that the information provided to potential recipients would include a clear indication of the possible neurologic consequences, specifically Guillain-Barre.

With the thanks of the Chairman to all participants for their very constructive participation in the meeting, it 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.


Chairman

January 13, 1977
Date