DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA

SUMMARY MINUTES OF MEETING

June 22, 1976

The Immunization Practices Advisory Committee met in Bethesda, Maryland, June 22, 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. Harry Meyer, Jr., Bureau of Biologics, FDA

Liaison

Dr. Samuel Katz, 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

Review Panel on Viral and Rickettsial Vaccines, Bureau of Biologics, Food and Drug Administration

CDC STAFF PRESENT

Office of the Center Director:	Dr. William Foege
Office of Information:	Mr. Donald Berreth
Bureau of Epidemiology:	Dr. Michael Hattwick Dr. Charles Hoke
Bureau of Laboratories:	Dr. Walter Dowdle Dr. Gary Noble
Bureau of State Services:	Dr. Lyle Conrad

OBSERVERS

Staff Members of Various Government Agencies
Representatives of the Mass Media
Representatives of Various Voluntary Health Agencies

Introduction

The meeting of the Immunization Practices Advisory Committee (IPAC) was held jointly with that of the Review Panel on Viral and Rickettsial Vaccines, Bureau of Biologics (Food and Drug Administration) in Building 29, National Institutes of Health, Bethesda, Maryland. Both the IPAC and the BoB Panel had attended a Workshop on Influenza on the previous day, Monday, June 21, 1976. The Workshop had been sponsored by the National Institute of Allergy and Infectious Diseases (NIH), the BoB, the Center for Disease Control, and the Department of Defense. The Workshop was a forum for presentation and discussion of data resulting from collaborative field trials of prototype influenza vaccines proposed for use in the National Influenza Immunization Program in the United States in 1976-77. The subsequent joint meeting of the BoB Panel and the IPAC was for follow-up discussions of data from the Workshop and consideration of other issues related to the national vaccination effort.

The joint meeting was opened at 9:00 a.m. by the two Chairmen, Dr. Saul Krugman for the BoB Panel and Dr. David Sencer for the IPAC. Initial discussion was on the agenda which was agreed should contain two principal items: 1) composition of vaccines for use in 1976-77, and 2) recommendations for using these vaccines, particularly with respect to the general population, to high risk groups, and under special circumstances such as pregnancy. There being many representatives of the mass media present, time was allocated to filming segments of the initial discussion.

Vaccine Composition

In general terms, data from the prior day's Workshop on rates of seroconversion by age, antibody responses, and reactogenicity of the various vaccines used in field trials were reviewed. It was generally agreed that antibody responses were very good in adults over approximately age 24 both in terms of rates of seroconversion and in acquired antibody levels. The responses in adults were essentially equivalent to 200 CCA and 400 CCA unit vaccines of both whole-virus and split-virus types. It appears that largely as a result of natural exposures, persons in the adult age group have had sufficient experience with somewhat comparable antigens to have essentially an "activated" immunologic system with respect to the swine antigen (A/New Jersey/76).

Pending more refined examination of the data with respect to the age at which good responses to swine influenza vaccine occur, it was generally believed that for the adult segment of the population, a vaccine with approximately 200 CCA units of either the whole-virus or split-virus type

would be suitable for single dose administration. Furthermore, using such a relatively low potency vaccine, side effects should be minimized, with less than 5 percent of adult recipients experiencing fever or other systemic symptoms.

Discussion of the less favorable antibody response of children 3-10 years and young adults 17-23 years was pursued at length. It would appear that a "priming" antigen stimulus by vaccination with a new influenza virus is very important with respect to those having no natural experience with comparable antigens. Such a "priming" stimulus may require a more potent or different kind of antigen. The fact that whole-virus vaccines, albeit more reactogenic than split-virus vaccines, appeared to be more reliable for initial immunization for the "un-primed" was emphasized. It was recommended that additional tests of prototype vaccines, dosages, and schedules be carried out in children and young adults in the immediate future to guide both the formulation of vaccines and recommendations for use in these age groups.

National Influenza Immunization Program

The concept of "stockpiling" influenza vaccines (for use only after a "real and present danger" was identified by actual swine influenza virus isolations or outbreak identification) in distinction to preparing vaccines and proceeding with nationwide immunization activities was discussed. Members both of the BoB Review Panel and the IPAC were aware that debate on this issue had been active in some sectors prior to the meeting. Although a few participants in the meeting were sympathetic with the concept of stockpiling, it was the overwhelming consensus of the IPAC and the BoB Review Panel that vaccine should be prepared and used. This was largely based on the continuing possibility for pandemic influenza caused by A/New Jersey/76, no new data to contradict this possibility, and the compelling information on the infeasibility of achieving any measure of adequate immunization of the country once cases or clusters of cases were occurring. In this regard, it was generally reported that once operational, most immunization programs would take two to three months to complete even if all elements functioned smoothly, and personnel, vaccine supplies, and other program ingredients were ample. In that once identified as causing cases, pandemic strains can be expected to become widespread in less than two months, there was seen to be no rational basis for a general "stockpiling concept." There was seen to be more risk in this concept when one adds a two-week period of antibody development onto the vaccination timetable.

Pregnancy

Dr. Charles Hoke of CDC reviewed an extensive literature analysis of potential adverse effects of influenza on maternal and fetal mortality, fetal anomalies, and neoplasia. In essence, although considerable anecdotal information on increased maternal mortality was recorded in the 1918-19 pandemic and to a more limited extent in 1957-58, the Committee was not persuaded that the risk of influenza with respect to adverse maternal or fetal effects was sufficiently well documented to designate pregnancy as an indication for promoting vaccination.

Although recognizing that many medical practitioners hesitate to give drugs, including biologics, to pregnant women, particularly early in pregnancy, the IPAC judged that available safety information on influenza vaccines, supported by that on other inactivated antigens, provided no evidence of a risk of influenza vaccination in pregnancy. Therefore, it was recommended that pregnancy not be designated as a contraindication to influenza vaccination.

Vaccine Side Effects

Dr. Hoke also presented an approximately 25-year review of medical literature and a schematic analysis of severe side effects from influenza vaccine. In Dr. Hoke's survey of medical literature, there were only ten instances of the occurrence of such reactions, mostly in adults. The reactions were primarily central nervous system phenomena such as encephalopathy which generally began within a day of to two weeks after vaccination. Essentially all cases recovered fully. In the survey there were only three references to fatal cases having some temporal association with influenza vaccine. The deaths occurred within minutes to days of the vaccination, and all involved evidence that causes other than influenza vaccine could have been responsible for the outcome.

In summary, as a result of its past knowledge and current review, the Committee views influenza vaccine as being exceedingly safe with respect to severe or disabling side effects. Usual doses are relatively commonly associated with minor local side effects such as transient redness and tenderness at the injection site and have the capability for inducing one to two days of low grade fever, myalgia, and malaise in several percent of adult recipients.

Other Business

The consensus judgments of the meeting are to be drafted by the Executive Secretary of the IPAC and distributed in the near future to Committee members for comment. In concept, the draft will result in a supplemental statement on influenza vaccine for publication to provide interim summary data and guidance for program development.

The meeting was adjourned by the Chairmen at approximately 3:30 p.m.

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

David J. Sencer 7/12/76

Chairman Date