DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA

SUMMARY MINUTES OF MEETING

May 1-2, 1973

The Immunization Practices Advisory Committee met in Atlanta, Georgia, May 1-2, 1973.

COMMITTEE MEMBERS PRESENT

Dr. H. Bruce Dull, Executive Secretary
Dr. Theodore C. Eickhoff
Dr. R. LeRoy Carpenter
Dr. Alexander D. Langmuir
Dr. E. Charlton Prather
Dr. Gilbert M. Schiff
Dr. Eleanor G. Shore

Ex Officio

Dr. John Leslie, Maternal and Child Health Service (Regional Medical Director, MCHS, Region IV)
Dr. Harry M. Meyer, Jr., Bureau of Biologics, Food and Drug Administration, DHEW

Liaison (American Academy of Pediatrics)

Dr. Samuel L. Katz

COMMITTEE MEMBERS ABSENT

Dr. David J. Sencer, Chairman

STAFF PRESENT

Epidemiology Program:	Dr. Philip Brachman
	Dr. Michael Gregg
	Dr. Robert Rubin
	Mr. Jere Housworth
	Dr. Richard Kaslow
	Dr. L. B. Schonberger
Laboratory Division:	Dr. U. Pentti Kokko
	Dr. Marion Coleman
	Dr. Thomas Monath
	Dr. James Nakano

Smallpox Eradication Program:	Dr. Philip Landrigan
State and Community Services Division:	Dr. J. Donald Millar
Immunization Branch:	Dr. John Witte
	Dr. J. Lyle Conrad
	Mr. Donald Eddins
	Dr. Joel Meyers
	Dr. Roger Barkin
	Dr. David Brandling-Bennett

OTHERS PRESENT:

Dr. Paul Parkman
Bureau of Biologics, Food and Drug Administration, DHEW

The meeting was called to order at 8:30 A.M. by the Executive Secretary acting for the Committee's regular Chairman, who was unable to attend. It was announced that Dr. Mary McLaughlin had, by necessity, resigned from Committee membership. A successor has not yet been named. Dr. John Leslie, Regional Medical Director (MCHS), in Region IV was introduced. He was attending as a representative of the Maternal and Child Health Service. Dr. Alice Chenoweth, erstwhile ex officio member from MCHS, is now retired.

The tentative agenda was reviewed. It was agreed that only the highest priority topics could be satisfactorily reviewed at this meeting - the remaining to be postponed.

Dr. Harry Meyer, ex officio Committee member from the Bureau of Biologics, described the effectiveness review panels being established by the Bureau for the purpose of considering the efficacy of existing biologics. Only the Steering Committee and one of three anticipated panels (on allergens and related bacterial products) have as yet been appointed. It is estimated that up to two years will be involved in deliberations. Liaison with consumer, professional, and Governmental agencies is being developed.

Dr. Meyer described the very recent demonstration by the Bureau of the presence of bacteriophages in some live virus vaccines produced in cell culture. The source(s) of these phages appears to be fetal bovine serum. An Ad Hoc advisory committee to BOB met on April 28, 1973, in Washington to consider this finding. The group reviewed existing data on bacteriophage with respect to human health and concluded that there was no known hazard. It agreed that ideally bacteriophage should be excluded from vaccines. Until this can be accomplished, it urged that vaccines should continue to be released and used.

The Bureau intends soon to publish a regulation in the Federal Register indicating detection of bacteriophage in some live virus vaccines and adjusting existing language on extraneous organisms in products for release and use until such time as bacteriophage can be excluded without altering safety, potency, purity, and effectiveness.

INFLUENZA

Traditional at its spring meeting is a full discussion of influenza. The 1972-73 type A influenza outbreak in the United States was considered to be moderately extensive, accompanied by excess mortality in many of the country's Regions. New techniques of surveillance, which included collaborating laboratories, hospitals, and schools in most States and many large cities, provided data which variably correlated with other indices of epidemic influenza. The laboratory aspects of surveillance activities considerably improved early identification of focal outbreaks.

The appearance in 1972-73 of an antigenically distinctive type B influenzavirus, B/Hong Kong, was described in relationship to focal, geographically scattered epidemics. Data were considered insufficient as yet by the Committee to forecast the likelihood that the new strain will become generally prevalent. It is obvious from laboratory studies on antigenic characteristics that there is little to no specific immunity to B/Hong Kong in the general population and little evidence that vaccine-induced immunity following commercial vaccines incorporating B/Mass can be expected to provide much protection against B/Hong Kong.

Dr. Gregg briefly reviewed a recent NIH influenza workshop in Houston, Texas, one largely devoted to considering studies of live influenza-virus vaccines. He concluded that some of the work was encouraging in showing vaccine immunogenicity and evidence of protection against influenza challenge but that considerable, additional testing and experience are needed before public health utility could be assessed.

Mr. Housworth, in reviewing data on influenza vaccine utilization reflected in the 1972 Immunization Survey, pointed out that the chronically-ill segment (estimated) of the population had received approximately two times more vaccine than others. He presented preliminary data from his own work on the age distribution and preexisting-illness status of fatalities during recent epidemic periods. His data indicate a variability in the lower-age cutoff point of statistically significant excess mortality and show a periodic absence of excess mortality in some of the very elderly age groups. He proposed that this latter phenomenon may represent preexisting immunity from childhood exposure to similar influenzavirus strains.

Dr. Eickhoff described an investigation of protection with commercially available influenza vaccine in recruits at the Lowry Air Force Base, Colorado, during the fall of 1972. Although the study was not, in all senses, a strictly double-blind, placebo-control evaluation, there was evidence of an approximately 60% protection against influenza (serologically diagnosed) among those receiving vaccine, in contrast to the unvaccinated. Differences were statistically significant although attack rates in study groups were low, approximately 2% and 5%.

Dr. Parkman indicated that the influenza vaccine for 1973-74, proposed before full recognition of type B/Hong Kong influenzavirus, is for a 1,000 CCA unit (minimum) bivalent product including, proportionately, 700 CCA units of a type A antigen comparable to A/England/42/72 and 300 CCA units of type B/Massachusetts/1/71. Meetings with manufacturers in the near future will consider the implications of the new type B/Hong Kong influenzavirus with respect to future vaccine formulation.

ATTENUATED SMALLPOX VACCINES

Dr. Parkman reviewed the status of investigations and experience with CV-1 attenutated smallpox vaccine. He asked the Committee for informal comment

regarding its perceived need in public health practice for an attenuated smallpox antigen. The Committee acknowledged the apparent effectiveness of CV-1 as an initial immunizing agent, recognizing, however, that confidence in protection against smallpox could only be gained by subsequent vaccination with a standard smallpox antigen. Because the need for an attenuated smallpox vaccine is currently small and because of the general availability of Vaccinia Immune Globulin (VIG) for problem cases of smallpox vaccination, the Committee saw no reason to encourage further attenuated smallpox vaccine research and development at the present time.

SIMULTANEOUS USE OF CERTAIN LIVE VIRUS VACCINES

Drs. Brandling-Bennett and Parkman reviewed a topic discussed at previous meetings and provided additional data on the immunologic comparability of simultaneously giving commercially available monovalent measles, mumps, and rubella vaccines from various manufacturers and giving the licensed combination products. The Committee reviewed these findings and encouraged the information be incorporated into its relevant vaccine recommendations.

Dr. Parkman presented studies on the stability of some live virus vaccines once distributed for use. He concluded that although there is evidence of some decline in potency, sufficient virus persists to give good responses. He also described a collaborative 5-year follow-up (with CDC) of persistence of polio antibody titers following a 3-dose and 4-dose vaccine dosage in infants. It was demonstrated that antibody declines in the two groups were essentially parallel. The Committee judged that the fall-off in titer reconfirmed the value of giving regular school-entering booster doses several years after the primary series in infancy.

YELLOW FEVER/SMALLPOX VACCINATIONS

Dr. Monath reviewed published information on the interference between smallpox and yellow fever vaccines given in sequence. Data from some recent studies are generally persuasive that no appreciable interference in fact occurs. It was recommended, however, that additional laboratory tests using serologic and other methods of a more classical sort would be valuable before modifying ACIP statements.

ZOSTER IMMUNE GLOBULIN

Dr. Joel Meyers reviewed data on the prophylaxis of varicella with herpes zoster immune globulin (human) (ZIG) derived in the course of CDC's distributing ZIG to high-risk patients--mainly those with impaired immunologic responsiveness and conditions enhancing risk from varicella. The data suggest moderate protection against disease and/or an ability to modify varicella. However, optimally controlled field trials have not been carried out. Because the demand for ZIG far exceeds the supply, sequential observations on treated and untreated cases have been used as a basis for preliminary analysis. The Committee encouraged that as soon as possible, further investigations be undertaken to obtain definitive data on effectiveness and optimal dosage schedules.

POLIOMYELITIS

Dr. Schonberger reviewed data on the surveillance of polio in the United States, noting a continued decline in cases. Much of the information in his presentation was derived from a recently distributed poliomyelitis surveillance report (Neurotropic Diseases Surveillance, Poliomyelitis, 1971, dated March 1973.) He also discussed the annually updated analysis of reported instances of paralytic disease associated with receiving polio vaccine or contact with a vaccine recipient. It was pointed out that data do not provide sufficient information with which to assess the true risks because valid estimates of the "at risk" denominator groups are not available. This deficit is particularly notable for recipient-contact cases because a suitable denominator estimate requires correction not only for the number of contacts of vaccine recipients but also the immune status of these contacts.

The Committee reviewed with Dr. Nakano the limitations on specifying marker characteristics of excreted poliovirus with respect to vaccine-like or wild-like characteristics. In general, types 2 and 3 polioviruses retain vaccine-like markers considerably longer than type 1. The time of specimen collection and technical matters must be evaluated in judging the likely origin of polioviruses.

The Committee recommended continued investigation, review, and publication of data on vaccine-recipient and recipient-contact associated paralysis in order to document the extent and trends of these occurrences. It was generally considered that the currently reported instances of vaccine associated illness are consistent with past experience and underscore the need to encourage regular and complete immunization of all infants and children to establish immunity early in life. Further discussion was recommended for future meetings.

GROUP IMMUNIZATION

Dr. Kaslow discussed with the Committee his efforts to adapt ACIP recommendations on hospital employee immunization to a summary specifically addressing immunization in the hospital setting. The Committee encouraged this concept and agreed to review material which Dr. Kaslow has under development.

WORKING GROUPS

The Committee was divided into two working groups on Day 1 of the meeting. One group was asked to prepare a draft statement on influenza and the second to review current measles, mumps, and rubella statements with respect to considering necessary modifications. On Day 2, these documents were provided to the Committee for general consideration. Because sufficient time was not available to complete its review, the Committee chose to continue the process by correspondence and deliberate on remaining subjects in detail at the fall session.

Prior to adjourning, the Committee selected October 9 and 10, 1973, as tentative dates for its regular fall meeting.

The meeting was adjourned at 4:30 P.M., May 2, 1973.

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

Acting Chairman

May 11, 1973
Date