Major Kenneth F. Burns, VC
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Dear Major Burns:

Enclosed you find your manuscript, entitled, "Japanese B Encephalitis Vaccine Field Trial in Okayama Prefecture, Japan - 1949." I was very glad to have an opportunity to read it and deeply regret to have had to delay so long in sending you the comments which you requested.

Although the form of this manuscript is one which would be expected in a paper that is to be submitted for publication, I note in your letter of 22 December 1950 that "this particular draft is intended as an intramural report." You go on to say further:

"One of the most embarrassing situations in our scientific relationship is the fact that Japanese Public Health authorities have never been given a complete record of the field trials conducted in Okayama. Col. Hullinghorst has suggested that I compile all of this material for the years 1946 through 1950 and present this manuscript to them (rather belatedly) as an offer of good intent."

As you well know, this particular project in Okayama was begun by me as Field Director of the Commission on Virus and Rickettsial Diseases after careful consultation with General Sams and a number of officials representing the Japanese Ministry of Health. The work of 1946 under my direction was carried out in the most intimate cooperation with the Japanese physicians designated to participate in this study. I do not know the details of Japanese participation during the years of 1947 and 1948 when Colonel Tigertt had supervision of this project. At any rate, I think that if any publication whatever is to be made of this extensive and laborious study, it would have to be done under the senior authorship of Japanese investigators with or without the names of those Americans who did most of the work between 1946 and 1950. It is
important to remember that from the American point of view the objectives of this investigation were to be fulfilled even though there should be no publication of the results. At any rate, I should like to ask you and Colonel Mullinghorst to postpone further action in this matter until the Commission on Virus and Rickettsial Diseases has had an opportunity to discuss this subject at its forthcoming meeting at the Army Medical School on 18 January 1951.

Although the manuscript itself contains a good deal of interesting information, I regret to say that it lacks the very information that I would personally regard as being most essential for a proper evaluation of the effects of the vaccine. You will find a number of handwritten comments in the body of the manuscript, but I should like particularly to stress the following:

1. You state that of 118 cases of suspected Japanese 
  encephalitis, 109 were confirmed clinically. Although under "Case Evaluation" you state that in some instances serum specimens were obtained from suspected cases, you give no indication how many of the 109 "clinically confirmed cases" were confirmed serologically. In my own opinion, only serologically confirmed cases should be considered in this analysis. Furthermore, I find it regrettable that only two autopsies were done on the twenty fatal cases. Certainly, there must have been Japanese pathologists available who could have collaborated in this work.

2. I deeply regret that I find the serological data recorded in Tables 7, 8, 9, 10, 11 and 12 obscure and uninformative. Perhaps the answers are present in your records, but I can find no answers in the tables just mentioned to the following questions which I regard as essential for this type of analysis:

   a) What proportion of the children who were vaccinated prior to 1949 had antibody in the blood before the booster dose given in 1949? And how did the incidence of antibodies in this group compare with unvaccinated controls of the same age in the same communities?

   b) What proportion of children vaccinated prior to 1949 who were negative before the booster dose in 1949 became positive thereafter?

   c) What proportion of the children who were without antibody prior to preliminary vaccination in 1949 developed such antibody after the third dose of vaccine?
d) What was the antibody pattern in the acute and convalescent serum specimens of the four vaccinated children who developed "clinically confirmed" cases of Japanese B encephalitis?

I hope very much that information to answer the above questions is available for the different years of this study. If the information is available, it would be most helpful to dig it out and tabulate it under the headings just mentioned. If it is not available, the data will be seriously deficient.

I was interested to note in your letter of 22 December 1950 that a statistical analysis of the incidence of Japanese B encephalitis in Okayama for 1950 still showed "a significant difference in morbidity between the vaccinated and unvaccinated individuals," even though no further vaccine was administered in 1950.

I am very grateful to you for sending me this information, and I hope you will understand the friendly spirit in which I am sending you these critical comments. I don't know how long it takes for the "Proceedings of the Society for Experimental Biology and Medicine" to reach Tokyo, but you may be interested to learn that your paper on "Congenital Japanese B Encephalitis Infection of Swine" appeared in the November 1950 issue.

With all good wishes for the coming year, I am

Sincerely yours,

Albert B. Sabin, M. D.

ABS/maj

cc Dr. Paul
Dr. Hammon
Lt. Col. Tigertt