

IMMUNIZATION OF AMERICANS WITH THE BIKEN JAPANESE
ENCEPHALITIS VIRUS VACCINE

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OBJECTIVE : To assess the immunogenicity of the Biken JEV vaccine in caucasians.

BACKGROUND : Encephalitis caused by infection with the Japanese Encephalitis virus is a major disease problem throughout SEA. Previous trials of the only currently available vaccine (Biken Co., Osaka, Japan) in Americans produced conflicting results, but in the main suggested that the vaccine was poorly immunogenic in flavivirus non-immune Caucasians. In 1979 the U.S. State Department elected to inoculated U.S. Peace Corps and U.S. AID personnel stationed in Nepal with the Biken vaccine. A prospective blinded cooperative study was designed to critically evaluate the immunogenicity of the Biken JEV vaccine in Americans.

METHODS : The study group consisted of 55 subjects. Twenty were associated with the American diplomatic mission or with U.S. AID. Two of these subjects were dependents 9 years of age; the remainder were aged 29 through 62 years. Three adult subjects were of non-American extraction (one each from Columbia, Pakistan, and Philippine origin). In addition 35 Peace Corps volunteers participated in the immunization series. Completion of the full immunization program with 3 serum titers, particularly a post-immunization titer was hampered by remoteness of the work/residence sites for many of the volunteers.

Lyophilized vaccine was obtained from Biken in Osaka and shipped to Kathmandu refrigerated on ice by commercial air freight. Upon receipt the vaccine was stored at 4°C until being reconstituted with diluent per the manufacturers instructions. Reconstituted vaccine was refrigerated at 4°C then discarded after one week if not used.

All subjects received a series of three intramuscular injections of 1.0 cc Biken JBE vaccine. Immunizations were administered on days 0, 7-14, and day 28. Serum was drawn on day 0 (pre-immunization), on day 28 (mid-immunization) and from one to seven weeks after the last immunization (post-immunization). Sera were split with aliquots being submitted to each of the three participating labs; AFRIMS, NIH, and Biken. Specimens were coded with alphabetical tags so that none of the labs was aware of whether a sample was a pre, mid, or post immunization titer. All sera were shipped on ice and hand carried by courier aboard commercial airlines from the American Embassy Clinic in

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Kathmandu to the respective labs. Serum titer reports were submitted by each of the labs and thereafter decoded by the medical staff of the embassy clinic.

RESULTS : The percent of specimens with detectable neutralizing activity before and after the immunization sequence as determined by each laboratory on the coded specimens were : AFRIMS 5% → 60%, NIH 40% → 92%, Biken 6% → 83%. A more detailed data analysis is in progress and plans are being made to extend the study to a second year.