

ABSTRACT

Summary of Experimental Design and Data Relating to Efficacy of Wyeth 21201 Cholera Toxoid

by

George Curlin

The Cholera Research Laboratory field-tested a glutaraldehyde toxoided preparation with protamine and aluminium phosphate adjuvants (Wyeth Laboratories, Lot No. 21201) during the post-monsoon 1974 cholera epidemic in Matlab Vaccine Trial Surveillance area. Volunteers from within the VTS area were preassigned to toxoid immunized group (A) or diphtheria pertussis placebo immunization (B). Volunteers were actively recruited from among the population aged between 1 and 15 years, and women about 15 years of age. Approximately 45,000 individuals received the first of two injections over a 33-day period. The second injection was given to approximately 74% of the above mentioned groups 42 days after the first injection. Each volunteer from every 33rd family included in the field trial was bled by a finger-stick just prior to the first injection, just prior to the second injection, and six weeks after the second injection in a serological survey. Cases were detected by two means:

- a). patients complaining of diarrhea and coming to the CRL hospital in Matlab who were shown to have positive rectal swabs for Cholera were counted as either out-patient or hospitalized cases depending on the severity of their diarrhea;
- b). Each member of the bari of 54 index cases of cholera were prospectively swabbed for ten days in their homes to detect mild cases and asymptomatic infections of cholera.

The cholera epidemic in the VTS area began concurrently with the vaccination campaign. This allowed the unique opportunity of assessing the efficacy of the vaccine stated in terms of time from the date of the last injection. The data indicate a measurable protection against Ogawa and Inaba cholera immediately after injection. The protection against Ogawa cholera waned rapidly and the protection against Inaba cholera waned after 9 weeks. The overall statement of efficacy through December 31, 1974, for hospitalized and out-patient Inaba and Ogawa cholera was 18%.

It was concluded that two intra-muscular injections of 100 micrograms of Wyeth 21201 toxoid did not offer levels of protection sufficient to be at all encouraging.

PROCEEDINGS OF THE 9TH MEETING OF THE SCIENTIFIC
REVIEW AND TECHNICAL ADVISORY COMMITTEE OF
THE CHOLERA RESEARCH LABORATORY

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and

REPORTS OF THE COLLABORATIVE STUDIES BETWEEN CENTER
FOR MEDICAL RESEARCH AND CHOLERA RESEARCH
LABORATORY

For the
YEAR 1974

Dacca, Bangladesh