

CHOLERA RESEARCH LABORATORY

Technical Committee Meeting
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RESEARCH SUMMARY

- Title : Cholera Toxoid Field Trial
- Author(s) : Dr. George Curlin, Mr. K. M. A. Aziz, Dr. Mizanur Rahman, Dr. Richard Levine and Dr. Willard F. Verwey
- Objectives : To test the field efficacy of a highly purified cholera toxoid in preventing clinical cholera in rural Bangladesh.
- Significance : There is much scope for improvement in cholera immunoprophylaxis. Other preventive measures are very inadequate for this ubiquitous, lethal disease in the subcontinent. At the moment preventing the mortality through prompt, cheap, therapy is our best defense against the ravages of cholera. If efficacious immunoprophylaxis were available a significant cause of childhood mortality could be avoided in Bangladesh.
- Current status of work : The field trial was completed on schedule. 92,838 participants between ages of 1 - 14, both male and female and adult women were included in the study. 75% of these participants received each of two injections of 100 mcg. of cholera toxoid. In summary the efficacy was noted only against Inaba disease and was in the neighborhood of 40% during the first quarter. However, in the second quarter (during which time there was very little cholera and therefore inadequate numbers of cases were seen to make a statistical statement about efficacy) and in the last half of the year no efficacy was noted against either Inaba or Ogawa disease. We feel the basic question of the biology of cholera toxoid has been answered. Owing to the tremendous number of cases seen among the field trial population, a statistically significant overall protection was seen although the degree of protection was far too small to warrant continued research with a purified material.
- Future Plans : It should be a topic of tense debate whether other work on cholera toxoids with or without the addition of somatic antigen should be conducted. The entire question of the route of administration (oral vs. intramuscular) of immunoprophylactic agents should be discussed early because the lag time between development of a prototype and field testing is considerable. ~~It has not been~~

For Presentation

For conference and consultation