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Flexibility of Oral Cholera Vaccine Dosing—A Randomized Controlled Trial Measuring Immune Responses Following Alternative Vaccination Schedules in a Cholera Hyper-Endemic Zone

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ABSTRACT

Background: A bivalent killed whole cell oral cholera vaccine has been found to be safe and efficacious for five years in the cholera endemic setting of Kolkata, India, when given in a two dose schedule, two weeks apart. A randomized controlled trial revealed that the immune response was not significantly increased following the second dose compared to that after the first dose. We aimed to evaluate the impact of an extended four week dosing schedule on vibriocidal response.

Methodology/Principal Findings: In this double blind randomized controlled non-inferiority trial, 356 Indian, non-pregnant residents aged 1 year or older were randomized to receive two doses of oral cholera vaccine at 14 and 28 day intervals. We compared vibriocidal immune responses between these schedules. Among adults, no significant differences were noted when comparing the rates of seroconversion for V. cholerae O1 Inaba following two dose regimens administered at a 14 day interval (55%) vs the 28 day interval (58%). Similarly, no differences in seroconversion were demonstrated in children comparing the 14 (80%) and 28 day intervals (77%). Following 14 and 28 day dosing intervals, vibriocidal response rates against V. cholerae O1 Ogawa were 45% and 49% in adults and 73% and 72% in children respectively. Responses were lower for V.cholerae O139, but similar between dosing schedules for adults (20%, 20%) and children (28%, 20%).

Conclusions/Significance: Comparable immune responses and safety profiles between the two dosing schedules support the option for increased flexibility of current OCV dosing. Further operational research using a longer dosing regimen will provide answers to improve implementation and delivery of cholera vaccination in endemic and epidemic outbreak scenarios.

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