

Resource May 5, 2016

## Efficacy of a Single-Dose, Inactivated Oral Cholera Vaccine in Bangladesh

[Article published in The New England Journal of Medicine on 5-May-2016 by Qadri F. et al. \[1\]](#)

### ABSTRACT

**BACKGROUND:** A single-dose regimen of the current killed oral cholera vaccines that have been prequalified by the World Health Organization would make them more attractive for use against endemic and epidemic cholera. We conducted an efficacy trial of a single dose of the killed oral cholera vaccine Shanchol, which is currently given in a two-dose schedule, in an urban area in which cholera is highly endemic.

**METHODS:** Nonpregnant residents of Dhaka, Bangladesh, who were 1 year of age or older were randomly assigned to receive a single dose of oral cholera vaccine or oral placebo. The primary outcome was vaccine protective efficacy against culture-confirmed cholera occurring 7 to 180 days after dosing. Prespecified secondary outcomes included protective efficacy against severely dehydrating culture-confirmed cholera during the same interval, against cholera and severe cholera occurring 7 to 90 versus 91 to 180 days after dosing, and against cholera and severe cholera according to age at baseline.

**RESULTS:** A total of 101 episodes of cholera, 37 associated with severe dehydration, were detected among the 204,700 persons who received one dose of vaccine or placebo. The vaccine protective efficacy was 40% (95% confidence interval [CI], 11 to 60%; 0.37 cases per 1000 vaccine recipients vs. 0.62 cases per 1000 placebo recipients) against all cholera episodes, 63% (95% CI, 24 to 82%; 0.10 vs. 0.26 cases per 1000 recipients) against severely dehydrating cholera episodes, and 63% (95% CI, -39 to 90%), 56% (95% CI, 16 to 77%), and 16% (95% CI, -49% to 53%) against all cholera episodes among persons vaccinated at the age of 5 to 14 years, 15 or more years, and 1 to 4 years, respectively, although the differences according to age were not significant ( $P=0.25$ ). Adverse events occurred at similar frequencies in the two groups.

**CONCLUSIONS:** A single dose of the oral cholera vaccine was efficacious in older children ( $\geq 5$  years of age) and in adults in a setting with a high level of cholera endemicity. (Funded by the Bill and Melinda Gates Foundation and others; ClinicalTrials.gov number, [NCT02027207](#) [2].)

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