

PP Cholera vaccines: grading of scientific evidence

III: Duration of protection

Settings: Global

Question: What is the justification for recommending a booster dose of Dukoral™ or mORCVax™/Shanchol™ every 2 years*?

Conclusion: Moderate level of scientific evidence that in general, protection levels of >50% are not maintained for >2 years* after vaccination.

* With Dukoral™ a booster is recommended every 6 months for children 2-5 years

Quality assessment						Summary of Findings
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Quality
Efficacy/effectiveness of BS-WC/WC-rBS (Dukoral™) >2 years following immunization						
1	RCT	Serious**	No serious	No serious	No serious	Moderate
Efficacy/effectiveness of bivalentWC only vaccine (ORCVAX™/mORCVAX™/Shanchol™) >2 years following immunization						
1	RCT	Serious**	No serious	No serious	No serious	Moderate
1	OBS					

** Based on one long-term RCT only

Van Loon FPL et al (1996) conducted a randomized, controlled clinical trial among 62 285 children >2 years and adult women in rural Bangladesh to determine the protective efficacy against cholera of three doses of oral B subunit-killed whole cell (BS-WC) or killed whole cell-only (WC) vaccines. During 5 years of follow-up, there were 144 cases of cholera in the BS-WC group (Protective efficacy (PE) = 49%; P < 0.001), 150 in the WC group (PE = 47%; P < 0.001), and 283 in the control group. Protection by each vaccine was evident only during the first three years of follow-up; long-term protection of young children was observed only against classical but not El Tor cholera; 3-year protection against both cholera biotypes occurred among older persons, but at a higher level against classical cholera.

Thiem VD et al (2006) assessed the long-term protection afforded by a killed whole-cell oral cholera vaccine produced in Vietnam. Mass immunization of children and adults with the killed whole-cell oral cholera vaccine was undertaken in half of the communes of Hue, Vietnam, in 1998; the remaining communes were immunized in 2000. No cholera was observed in Hue until 2003, when an outbreak of El Tor cholera made it possible to conduct a case-control study. The overall vaccine effectiveness 3-5 years after vaccination was 50% (95% CI 9-63).

References on duration

van Loon FP, Clemens JD, Chakraborty J, Rao MR, Kay BA, Sack DA, Yunus M, Ali M, Svennerholm AM, Holmgren J. Field trial of inactivated oral cholera vaccines in Bangladesh: results from 5 years of follow-up. *Vaccine* 1996; 14(2):162-66.

Thiem VD, Deen JL, von Seidlein L, Canh DG, Anh DD, Park JK et.al. Long-term effectiveness against cholera of oral killed whole-cell vaccine produced in Vietnam. *Vaccine* 2006; 24:4297-4303.