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SHORT REPORT

Coverage and side-effects of oral cholera (Dukoral) vaccine in Department of Medical Research (Lower Myanmar)

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Orally administered cholera vaccines represent a potential new tool to prevent or control cholera outbreaks. The two-dose oral killed rBS-WC cholera vaccine is well tolerated and provides significant protection against cholera. Field trials conducted in Bangladesh and Peru [1, 2] showed that this vaccine confers a high level of protection: 85% after the second dose and still about 62% protection two years later, in adult vaccinees. Protection among children less than 5 years is high during the first 6 months and then decreases dramatically.

Cholera is endemic in our country with high seasonal variations. Cases usually occur during the beginning of rainy season from May to June. Although there have been no large outbreaks reported during the past few years, number in tenths of culture positive cholera cases have been reported from different townships all year round. When the rectal swab samples of April and May from North Okkalapa General Hospital were confirmed in National Health Laboratory, 35 isolates were positive for both serotypes (Inaba & Ogawa) of *V. cholerae* 01. During this year, in Yangon Division, tested/culture positive cholera have been reported as: 35/56 (Inaba>Ogawa serotype), 71/226 (Inaba=Ogawa) and 51/109 (Ogawa>Inaba) in March, April and May (up to 15th), respectively (personal communication, Bacteriology Section, NHL). Some of the divisions of DMR have to handle stool samples from which *V. cholerae* can be isolated. Therefore, the two-dose killed oral vaccine against cholera and ETEC diarrhea (Dukoral) was studied among our staff and their relatives in Department of Medical Research (Lower Myanmar) with an aim to assess acceptability, coverage and side effects of the vaccination.

Vaccine, one dose (3 ml) contains: *Vibrio cholera* 01 Inaba and Ogawa, Classical and El Tor strains approximately $1x10^{11}$ vibrios (heat/formalin inactivated) cholera toxin B subunit 1 mg, sodium dihydrogenphosphate, disodium hydrogen phosphate, sodium chloride and sterile water [3]. Since the vaccine is 99 acid labile, each dose was provided with a sachet of sodium hydrogen carbonate. Buffer solution was prepared by dissolving the sachet in 150 ml of water. The full dose of vaccine was mixed with 40, 75 and 150 ml of buffer solution, for persons 2-4 years, 5-11 years, and over 11 years, respectively.

This study was conducted from 7th May to 21st June 2009. In this department, the total numbers of staff and their relatives are 950 (583 females and 367 males). The two doses of vaccine were given at 7-day interval. The age, sex, volume of vaccine ingested by each individual were recorded at the time of first visit. The side effects were interviewed at the time of taking second dose.

Totally 1,664 doses were administered and vaccine coverage was: 849 (517 females and 332 males)/950 (89%) for first dose and 815 (492 females and 323 males)/950 (85.8%) for second dose. Among our staff, 101 (10.6%) had not received any dose of the vaccine. Among 849 vaccinees (383 staff

and 466 relatives), there were 14 and 20 drop-outs, respectively, and their complaints were diarrhoea and itchiness.

All the vaccinees who had taken 2nd dose were interviewed for acceptability, 779 (95.6%) said they liked the taste and took the 2nd dose. The remaining 36 (21 females and 15 males) (3.8%) had some side effects such as abdominal pain (31), dizziness (28), abdominal discomfort (20), loose motion (19), nausea and vomiting (9), headache (9) and non-specific complaints, including nausea, weakness and loss of appetite by seven.

In this study, vaccine coverage of the total numbers of staff and their relatives were 89% for first dose and 85.8% for second dose. Among our vaccinees, only 3.8% reported side-effects following its ingestion. It gives a high level of protection: 100% protection one year later, in studied vaccinees where there was still no cholera cases reported during May to July 2010.

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REFERENCES

1. Clemens JD, Sack DA, Harris JR, Van Loon F, Chakraborty J, Ahmed F, *et al*. Field trials of cholera vaccines in Bangladesh: results from a three-year follow-up. *Lancet* 1990; 335, 270–3.
2. Sanchez JL, Vasquez B, Begue RE, Meza R, Castellares G, Cabezas C, *et al*. Protective efficacy of the oral whole cell/recombinant B subunit cholera vaccine in Peruvian military recruits. *Lancet* 1994; 344:1273–6.
3. Manufacturer's Leaflet. DUKORAL: Vaccine against Cholera and ETEC Diarrhoea. SBL Vaccine AB, 105 21 Stockholm, Sweden.