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See Articles page e162

Although killed, whole-cell oral cholera vaccines (OCVs) have been known to be efficacious since 1986,[1] and the bivalent whole-cell vaccine Shanchol has been licensed in India since 2009,[2] OCV was not regarded as useful for controlling cholera outbreaks until recently.[2] Many public health officials questioned the use of OCV,[3] including concerns about its cost, the feasibility of undertaking large campaigns, the acceptability of OCV among vaccinated communities, and the possibility of diverting resources from other interventions. There was also uncertainty as to whether the vaccine, although known to be effective in endemic countries (eg, India or Bangladesh), would be effective in areas without a history of cholera, such as Haiti. When the cholera epidemic started in Haiti, Shanchol was not yet prequalified by WHO, and only a limited supply was available, so vaccination of large numbers of people was not realistic. Assuming effectiveness in Haiti, and if the vaccine had been available and had been used earlier, computer models suggest it could have averted many cases and deaths.[4-6]

Although cholera vaccine was not used in the first two main waves of the epidemic, pilot projects were done in 2012 to deliver Shanchol to about 100 000 people in urban and rural Haiti.[7,8] Subsequently, the Ministry of Health undertook larger campaigns in 2013, and plan to implement additional OCV campaigns in the coming years. Furthermore, the Ministry of Health has included the use of OCV in its national strategy for elimination of cholera, along with a continuing effort to improve water and sanitation. The earlier reports[7,8] showed that OCV was acceptable and that OCV campaigns were feasible in Haiti, but a new report by Louise Ivers and colleagues[9] in *The Lancet Global Health* provides important new information, showing that the vaccine's effectiveness in Haiti is comparable to that found in endemic countries of Asia and Africa.[10] Of 47 people with cholera, 33 (70%) self-reported vaccination versus 167 (89%) of 188 controls (vaccine effectiveness 63%, 95% CI 8–85). Conversely, there was no association between self-reported or verified vaccination and non-cholera diarrhoea (vaccine effectiveness 18%, 95% CI −208 to 78 by self-report and −21%, −238 to 57 by verified vaccination).

Similar efficacy and effectiveness of the two killed OCVs—Dukoral and Shanchol—has been documented. The two vaccines differ in that Dukoral is more expensive and is administered in a glass of buffer solution to preserve the B subunit component of the vaccine, which increases the logistic requirements for its use. By contrast, Shanchol, which has no B subunit, needs no buffer, is less costly, and consists of only 1·5 mL liquid, which can be consumed directly from a vial. Shanchol is now available through the OCV stockpile, which is supported partly by the Global Alliance for Vaccines and Immunization. It is being used primarily as a response to an outbreak, but it will probably also be used for groups at risk in endemic areas. Clearly, much work is needed to identify how best to use the vaccine in a manner that maximises its cost-effectiveness.[11]

Some of the limitations of this study are related to the small sample size, which is a common problem in cholera effectiveness studies and which limits the ability to discern differences among subgroups. In this study, the point estimates differed in some subgroup comparisons (eg, age group and time since vaccine administration), but the sample was not powered to identify whether these differences were real. Ivers and colleagues[9] were also not able to assess the potential for herd protection, which was found in other studies.[12,13] Although OCV protects vaccinated individuals, it also lowers the risk for unvaccinated neighbours if vaccine coverage is sufficiently high. Modelling work predicted that 50% coverage could avoid transmission in endemic areas.[14] Thus, further studies are needed to better understand how to maximise the effect of herd protection.

Because the vaccine is in short supply and because providing two doses is logistically more complex and costly than providing only one dose, there is interest in the use of a single dose, which allows vaccination for twice as many people with the same amount of vaccine. Studies are underway to assess the efficacy of a single dose and to compare the cost-effectiveness of a single-dose versus a two-dose regimen. Even if a single dose yields a lower level of effectiveness, it may still prevent more cases in a population than a two-dose strategy because the target population can be expanded, especially in outbreak settings. The field effectiveness of and the situations in which a single-dose strategy is appropriate still need to be identified.

Some additional constraints of the vaccine should be mentioned. The vaccine is registered to be kept cold, but the cold chain requirement adds to the logistics and cost of the campaign. The main antigen of Shanchol is a lipopolysaccharide, which is thermostable; hence, Shanchol has a vaccine vial monitor (VVM) category 14 (ie, if the vaccine is kept at 37°C, the colour endpoint at which discarding the vaccine is advised will be reached after 14 days). Extension to VVM category 30 would improve flexibility and reduce costs for campaigns.

Following previous practice, Ivers and colleagues[9] excluded pregnant women. Unfortunately, there is no coherence between the position of WHO, which recommends OCV for pregnant women because of their increased risk of complications and death when infected by cholera, and the package inserts, which stress the scarcity of safety data during pregnancy. Shanchol is a killed oral vaccine and is therefore expected to be safe, but additional data are needed to reassure regulators with regard to use during pregnancy.

Finally, will OCV eliminate cholera from Haiti? By itself, this seems unlikely, but when combined with improved water and sanitation, health education, and high-quality treatment, OCV can play a major part in reducing this infection to low levels and quicker than if OCV is not included in the plan.

The findings in this Article confirm that Shanchol is effective to protect individuals against cholera in endemic, epidemic, and intermediate contexts, and it complements previous work done by this group, which proved that OCV campaigns are feasible, well accepted, and can help to improve hygiene, water, and sanitation practices in vaccinated communities if they are well organised.[15] These research studies should serve to reassure and help the Ministry of Health of Haiti and ministries of health of other countries to make the most effective and efficient use of OCV, with the aim of eliminating cholera.

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