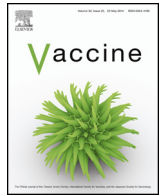




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Meeting report

Considerations around the introduction of a cholera vaccine in Bangladesh

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ABSTRACT

Cholera is an endemic and epidemic disease in Bangladesh. On 3 March 2013, a meeting on cholera and cholera vaccination in Bangladesh was convened by the Foundation Mérieux jointly with the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B). The purpose of the meeting was to discuss the investment case for cholera vaccination as a complimentary control and prevention strategy. The performance of a new low cost oral cholera vaccine, Shanchol™, used in recent trials in Bangladesh, was also reviewed in the context of a potential large-scale public-sector vaccination program. Findings showed the oral vaccine to be highly cost-effective when targeting ages 1–14y, and cost-effective when targeting ages 1+y, in high-burden/high-risk districts. Other vaccination strategies targeting urban slums and rural areas without improved water were found to be cost-effective. Regardless of cost-effectiveness (value), the budget impact (affordability) will be an important determinant of which target population and vaccination strategy is selected. Most importantly, adequate vaccine supply for the proposed vaccination programs must be addressed in the context of global efforts to establish a cholera vaccine stockpile and supply other control and prevention efforts.

1. Introduction

A meeting on cholera and cholera vaccination was convened by the Foundation Mérieux in partnership with the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B) on 3 March 2013 in Dhaka, Bangladesh. After the successful completion of several cholera vaccine trials in the country, the purpose of the meeting was to discuss vaccination as a complimentary control and prevention strategy as Bangladesh takes steps to become the first country to use cholera vaccine in a large-scale public-sector program.

In Bangladesh, cholera is an endemic and epidemic disease where thousands are hospitalized daily during monsoon season, and where there is increasing awareness of the frequency and severity of outbreaks associated with floods and other natural disasters. While case fatality has fallen dramatically with timely access to oral or intravenous rehydration therapy, the recent availability of a new low-cost vaccine with longer, more sustained protection, Shanchol™ (Killed Bivalent (O1 and O139) Whole Cell Oral Cholera Vaccine, Shantha Biotechnics Limited [1]), presents the opportunity for vaccination as a complementary strategy to help reduce the national cholera burden. Shanchol™ was prequalified by the World Health Organization (WHO) in 2011 [2].

2. Bangladesh immunization program

Bangladesh has a high performing Expanded Program on Immunization (EPI) with 90 percent of districts achieving 90+ percent vaccination coverage with DTwP–HepB–Hib pentavalent vaccine [3]. The introduction of pneumococcal conjugate vaccine (PCV-13)

and rotavirus vaccine (Rota-2) is planned for the coming years. Bangladesh eliminated neonatal tetanus (NT) in 2008. Starting in 2006 Bangladesh implemented a highly successful measles reduction campaign and measles–rubella vaccine was introduced in 2012.

Bangladesh was declared polio free in August 2000. Imported polio was detected in 2006 when 18 polio cases were reported and confirmed [4]. Indigenous transmission of wild poliovirus has again been controlled since 2007. An intensive effort to eliminate polio from Bangladesh includes an emphasis on a high performing EPI, National Immunization Days (NIDs) and mop-up campaigns, and the establishment of a strong Acute Flaccid Paralysis (AFP) surveillance system [5].

3. Cholera prevention and control

Cholera is an acute diarrheal disease that can kill previously healthy patients within hours if left untreated by oral or intravenous rehydration therapy [6]. Most deaths are in patients that do not seek care or do not reach a treatment facility in a timely way. Cholera exists both as an endemic and epidemic disease, and the explosive pattern of outbreaks is attributed to a short incubation period of two hours to five days. The majority of cholera endemic countries is found in Asia and sub-Saharan Africa and report an overall case fatality rate of less than five percent [6]. However, in outbreak situations among the most vulnerable groups, the case fatality rate can be up to 50 percent [6]. Although likely a gross underestimate due to under reporting, the World Health Organization (WHO) estimates cholera is responsible for 100,000–130,000 deaths and 3–5 million cases every year, globally [6].

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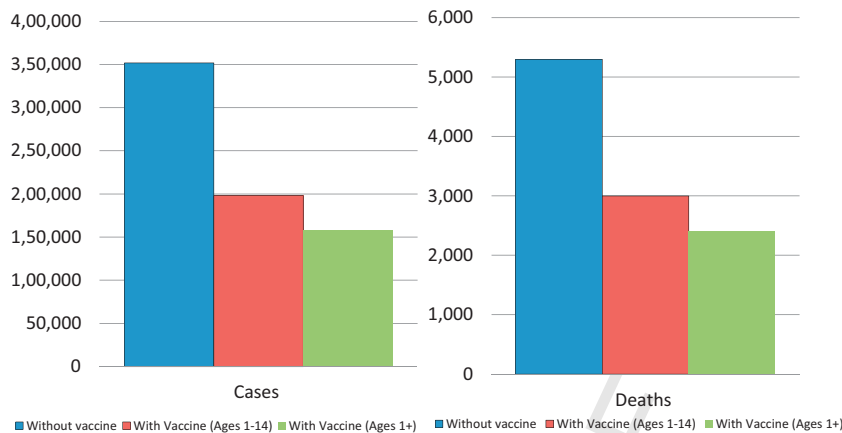


Fig. 1. (A, B) Estimated annual impact of cholera vaccination, ages 1–14 and 1+ in high-burden/high-risk districts, Bangladesh.

Over the last several years one hallmark of the global cholera burden is increased awareness of major cholera outbreaks. WHO currently recommends oral cholera vaccines for complementary use in endemic areas as well as areas at risk of outbreaks, including preemptive use in humanitarian emergencies [6]. Following the 2010 cholera outbreak in Haiti the World Health Assembly passed a resolution for WHO to develop updated and practical guidelines on the use of oral cholera vaccines in conjunction with other control strategies [7,8]. In 2011 WHO convened a working group to advise the creation of a vaccine stockpile specifically intended for outbreak response [9].

4. Cholera in Bangladesh

Endemic and epidemic cholera is a major public health problem in Bangladesh [10,11] and the entire national population (155 m people) is presumed to be at risk of disease [12]. There is no accurate data on the number of cholera cases and deaths in the country. Estimates suggest an incidence of approximately 450,000 cases per year [12]. During 2009, >2 million acute watery diarrhea cases were registered but the proportion that were cholera is unknown [13]. One study estimates that 22 percent of acute watery diarrhea may be cholera [14]. Multidrug-resistant [13] and El Tor strains of cholera have recently emerged in Bangladesh [15]. Multidrug-resistant and El Tor cholera are associated with more severe outcomes, longer hospital stays, and higher case fatality rates. Rapid urbanization is likely contributing to an increase in the rates of cholera in the country [16,17].

5. Findings

Throughout the course of the meeting, presentations highlighted the high performing EPI, the achievements and successes of accelerated disease control efforts and new vaccine introductions following the Bangladesh National Implementation Plan, cholera burden and cholera control and prevention policy, using models to evaluate vaccination strategies for epidemic and endemic cholera control, as well as the Bangladesh investment case for cholera vaccine and updates on cholera vaccine pilot projects in Bangladesh.

Cholera control and prevention strategies that do not include vaccination are well established and mostly effective, yet cholera remains poorly controlled in both endemic and epidemic contexts. Research findings presented by ICDDR, B reveal that new lower cost oral cholera vaccines can be a complementary tool to combat both endemic and epidemic cholera when coupled with access to safe

water, basic sanitation, good hygiene practices, and rehydration therapy and clinical treatment.

Major findings included:

Disease burden and economic burden: Cholera is an endemic and epidemic disease in Bangladesh with approximately 350,000 cases and 5300 deaths attributed to cholera annually [18]. It is also becoming an increasingly urban disease due to growing peri-urban slum populations and overburdened water and sanitation systems. ICDDR, B cholera surveillance indicates 28 of Bangladesh’s 64 districts are considered to be “high-burden” or “high-risk” for cholera [18]. Over half of the country’s population resides in these high-burden/high-risk districts. Cholera cost-of-illness in Bangladesh is estimated to be US\$6.3 million per year [18].

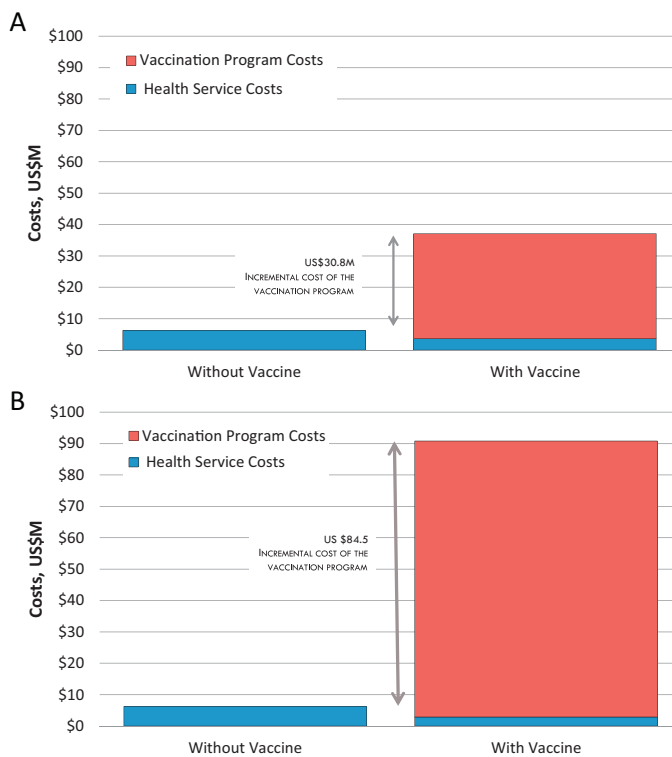


Fig. 2. (A) Health service and minimum program costs for cholera vaccination, ages 1–14 in high-burden/high-risk districts, Bangladesh (in million USD). (B) Health service and minimum program costs for cholera vaccination, ages 1+ in high-burden/high-risk districts, Bangladesh (in million USD)

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