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#### Review

# Typhoid vaccine introduction: An evidence-based pilot implementation project in Nepal and Pakistan

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#### ABSTRACT

The World Health Organization (WHO) in 2008 recommended the use of currently licensed typhoid vaccines using a high risk or targeted approach. The epidemiology of disease and the vaccine characteristics make school-based vaccination most feasible in reducing typhoid disease burden in many settings. To assess feasibility of school-based typhoid vaccination, two districts in Kathmandu, Nepal and two towns in Karachi, Pakistan were selected for pilot program. Vaccination campaigns were conducted through the departments of health and in partnerships with not-for-profit organizations. In total 257,015 doses of Vi polysaccharide vaccine were given to students in grades 1–10 of participating schools. The vaccination coverage ranged from 39 percent (38,389/99,503) in Gulshan town in Karachi, to 81 percent (62,615/77,341) in Bhaktapur in Kathmandu valley. No serious adverse event was reported post vaccination. The coverage increased for vaccination of the second district in Pakistan as well as in Nepal. There was an initial concern of vaccine safety. However, as the campaign progressed, parents were more comfortable with vaccinating their children in schools. Supported and conducted by departments of health in Pakistan and Nepal, a school-based typhoid vaccination was found to be safe and feasible.

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1. Background

Typhoid fever has been in existence since antiquity, with found in ancient Chinese text dating back to 100 AD [1]. Although this disease has been controlled in much of the industrialized world, it continues to affect people in many developing countries [2]. Based on previous global disease burden estimates, typhoid fever has the highest incidence in South Asia and Southeast Asia which constitute 90% of estimated global enteric fever cases (includes *Salmonella* Typhi and *Salmonella* Paratyphi A, B and C infections). However, recent estimates for Africa have reported incidences comparable to those in Asia, with reported outbreaks more common in Africa

\* Corresponding author. Present address: 2000 Pennsylvania Ave NW, Suite 7100, Washington DC 20006, USA. Tel.: +1 202 621 1698; fax: +1 202 842 7689. *E-mail address: khan.m.imran@outlook.com* (M.I. Khan). than in Asia [3]. Children and adolescents are the most affected age-groups in high endemic countries [4–6].

Typhoid fever is caused by the bacterium *Salmonella* enterica serotype Typhi (*S*. Typhi) and is spread by the fecal-oral route through contaminated food or water [7,8]. Typhoid fever is characterized by persistent, high-grade fever and abdominal pain; illness often lasts one month or more [9]. In about 10–15% of cases without appropriate antimicrobial therapy, it leads to serious complications, including hypotensive shock, perforation of the gut, and gastrointestinal hemorrhage [7]. Rapidly increasing rates of antibiotic resistance have increased the difficulty and cost of treatment and are threatening to increase case fatality from the currently estimated rates of 1-4% to the pre-antibiotic era rates of 10-20%[10].

Preventive measures include improved water and sanitation systems, but given the huge investment required, they are distant goals for most typhoid-endemic countries. In 2000 and 2007, the

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World Health Organization (WHO) recommended typhoid vaccination as a control strategy [11]. In its 2009 meeting, the WHO South East Asia Regional Office (SEARO) recommended prioritization of typhoid vaccines for "immediate" implementation.<sup>1</sup> However, typhoid vaccines have not yet been regularly used in typhoidendemic regions.

Safe and effective typhoid vaccines have been available since the early 1990s [12]. But public-sector use has been limited and they have never been used in a large scale vaccination program. In response to this, the International Vaccine Institute's Vi-based Vaccines for Asia (VIVA) Initiative accelerated the adoption of the typhoid Vi-polysaccharide vaccine in high risk areas. To determine program feasibility and population acceptance of typhoid vaccination, pilot typhoid vaccination programs were carried out in two districts in Kathmandu, Nepal and two towns of Karachi, Pakistan.<sup>2</sup> Nepal and Pakistan were selected based on their high disease burden, their previous use of typhoid vaccines, and their governments' willingness to take the lead in the conduct of the vaccination campaigns. A school-based vaccination campaign was designed for this project, as governments in the Southeast Asia region have demonstrated that school-based programs are an effective approach for achieving high coverage [13–15]. Furthermore, since approximately 70% of cases occur in children less than 15 years of age in high risk regions [16], vaccinating students will likely be critical for the reduction of typhoid fever disease burden.

#### 2. Methods

#### 2.1. Planning phase

#### 2.1.1. Designing the pilot vaccination program

Key stakeholders needed to implement the pilot typhoid vaccination program were identified. In both countries, the key stakeholders included government public health officials (Department of Child Health, Ministry of Health and Population in Nepal; and the Expanded Program on Immunization, Ministry of Health, Sindh, in Pakistan), pediatricians, academics, and, in the case of Nepal, the Program for Immunization Preventable Diseases Office of WHO. A series of discussions with these stakeholders were held to identify: (1) the sites for vaccination; (2) target ages for vaccination; (3) the modality of vaccine introduction; and (4) support organizations and groups required for vaccine introduction.

Upon discussion with government officials, it was found that participation of the government immunization program was essential for the planning, management, and execution of the pilot vaccination program. Their recommendation was to share the tasks. The local governments in Nepal agreed to conduct the vaccination, whereas the Trust for Vaccines and Immunization (TVI) took the lead in Pakistan with support from the Ministry of Health. Due to extensive nature of research data collection, public officials suggested that other non-governmental agencies could be involved in planning, managing, recording, and analyzing the results of the pilot vaccination program.

#### 2.1.2. Study geographic setting

When deciding on the pilot vaccination sites, the key stakeholders suggested considering: the number of doses available;

<sup>1</sup> http://www.who.int/immunization/sage/Report\_SEARO\_Vaccine\_ Prioritization\_wshop.pdf. previous experiences in piloting national vaccination program(s); existing collaborations between health and education bodies; and potentially influential districts/towns, so that the success of the program could inform other districts/towns. In Nepal, the pilot school-based vaccination programs were planned in two districts of the Kathmandu Valley, Lalitpur and Bhaktapur. In Pakistan, they were planned in two out of 18 towns in Karachi, Gulshan and Jamshed.

#### 2.1.3. Study population and eligibility criteria

The target for the school-based vaccination was children in grades 1-10 (approximate ages 5-15 years old). The governing bodies for public and private schools are different in both countries. These entities were repeatedly visited and informed about the benefits of vaccination, and subsequently included in the program. In Pakistan, an important addition was the religious schools, *madrasahs*, which were in neither the public nor private school systems.

#### 2.1.4. Advocacy and endorsement

Appropriate approvals and support for the vaccination program were sought from relevant local authorities in both countries. This process was initiated in partnership with key stakeholders. The first step was to gain the support of local authorities through repeated advocacy visits, and providing scientific information on the disease, preventive methods, available vaccines, and the profile of the Vi polysaccharide vaccine. In response to the advocacy visits, local authorities granted the necessary approvals and support to facilitate social mobilization activities.

### 2.1.5. Formative research, social mobilization, and communication activities

Since typhoid vaccination is not routinely done in these countries, and a range of stakeholders (e.g., parents, health care providers, community representatives, religious leaders, and school and health officials) were involved, it was deemed necessary to inform and mobilize these groups to increase participation in the school-based typhoid vaccination. Formative research was conducted among parents, teachers, and local health care providers to assess their perceptions, knowledge, attitudes, and interest in typhoid fever and use of the Vi polysaccharide vaccine against the disease. We also explored credible and common sources of information for acquiring additional knowledge about the disease and the vaccine. The study was conducted between June 2009 and March 2011 in Nepal and Pakistan.

The project utilized a comprehensive communication strategy that took into account the concerns and questions of the target groups. IEC materials (brochures, posters, flyers, and banners), radio jingles, television announcements, and a documentary were developed and pre-tested. Additionally, a series of orientation meetings was carried out with teachers, students, and parents when requested by school staff.

#### 2.1.6. Social mobilization monitoring

To assess social mobilization and communication strategy, head teachers and parents were regularly interviewed during the course of the field implementation.

#### 2.2. Vaccination campaign

#### 2.2.1. Strategy development and training

Standard operating guidelines were developed for the vaccination activities. Vaccinators and other staff were trained on the nature of typhoid fever, the typhoid vaccine, safe injection practices, adverse event following immunization (AEFI) management,

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<sup>&</sup>lt;sup>2</sup> Vi-based Vaccines for Asia (VIVA) Initiative: The Vi-based Vaccines for Asia (VIVA) Initiative was a 5-year project implemented by the International Vaccine Institute. The VIVA Initiative aims to reduce the burden of typhoid fever in developing countries through the adoption of Vi-polysaccharide vaccines, and the development, testing, and licensure of affordable next-generation Vi-conjugate vaccines.

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