Typhoid: Study confirms typhoid conjugate vaccine is safe and immunogenic in children under age 2

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A new study conducted by IVI in collaboration with SK bioscience shows that single-dose and two-dose regimens of Vi-DT typhoid

conjugate vaccine (TCV) are safe and immunogenic in children six to 23 months of age, a group with high rates of typhoid fever in resource-limited settings. The findings from this study, newly published online in *EClinicalMedicine*, describe the successful completion and analysis of a Phase II clinical trial of Vi-DT six months after vaccination.

The World Health Organization (WHO) recommends TCVs for use in endemic settings with Gavi, the Vaccine Alliance providing the vaccines to eligible countries. However, with only one TCV pre-qualified by the WHO, demand currently exceeds supply. This study is a critical step toward gaining licensure and WHO-prequalification of an additional TCV to increase the global stockpile.

"Our findings show that a single dose of conjugated Vi-DT vaccine is safe and provides anti-Vi seroconversion rates similar to the two-dose regimen in children between six months and two years of age," said Dr. Birkneh Tilahun Tadesse, a Research Scientist at the International Vaccine Institute (IVI), which conducted the study at the Research Institute for Tropical Medicine in Manila, the Philippines.

"This is an important advance, considering the significant burden of disease in infants and young children, and our goal remains developing a safe, single-dose vaccine with long-lasting immunogenicity to protect more children against typhoid fever," said Dr. Sushant Sahastrabuddhe, Director of the Typhoid Program at IVI.

Increasing global supply of typhoid conjugate vaccines

Vi-DT was developed at IVI and its technology was transferred in 2013 to SK bioscience in South Korea for manufacturing and commercialization. A Phase I safety trial of Vi-DT was first conducted

in the Philippines with participants 2-45 years of age and showed that the vaccine was safe and immunogenic four weeks after first dose. Following the successful completion of a Phase II trial with infants under 2 years, large-scale Phase III studies with a single-dose of Vi-DT have started in the Philippines and Nepal in 2020.

The WHO recommends programmatic use of typhoid vaccines to prevent and control typhoid fever with preference for TCVs for their longer-lasting protection, fewer doses, and suitability for children under 2. For treatment, antibiotics are currently the frontline intervention for typhoid fever, but drug-resistant typhoid has emerged across Asia and Africa, highlighting the need for sufficient supply of TCV and sustainable vaccination programs.

More information: Maria Rosario Capeding et al, Safety and immunogenicity of Vi-DT conjugate vaccine among 6-23-month-old children: Phase II, randomized, dose-scheduling, observer-blind Study, *EClinicalMedicine* (2020). DOI: 10.1016/j.eclinm.2020.100540

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