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Methodology, results and lessons-learned from the phase I to IV clinical trials with all three FDA licensed *Rotavirus* vaccines in Bangladesh

Safe and effective *Rotavirus* vaccines are needed to reduce the enormous public health burden associated with *Rotavirus* illness, especially in developing countries. Prevention by vaccination is critical for effective control of *Rotavirus* infection since it cannot be prevented with improvements in water and sanitation. The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B) has completed several *Rotavirus* vaccine (RV) trials which ranged from phase I to licensure and post marketing evaluation of the vaccines (phase IV). Three FDA (USA) licensed *Rotavirus* vaccines were tested and evaluated in these trials: Tetravalent rhesus *Rotavirus* vaccine (RRV-TV, Rota Shield, Wyeth Lederle), Pentavalent *Rotavirus* vaccine (PRV, RotaTeq®, Merck & Co.) and monovalent *Rotavirus* vaccine (Rotarix®, GlaxoSmithKline). The trials were conducted in urban and rural areas and the sample size ranged from few hundreds to several thousands. The safety, immunogenicity, efficacy and effectiveness of the vaccines were evaluated. RV did not interfere with the immunogenicity of oral polio vaccine and measles and rubella vaccine. The efficacy and effectiveness of the vaccines were 40-45%. Inclement weather, difficult transportation, and movement of study participants were some of the challenges identified. Bangladesh Government is actively thinking to introduce RV vaccine into EPI program and adequate cold chain facilities need to be established. Details of the methodology, results, lessons-learned and challenges for successful implementation of these trials will be presented.

Biography

K Zaman has been working as Senior Scientist and Epidemiologist at the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B), in the Infectious Diseases Division. For the last 35 years, he has gained extensive experience in the design, implementation, and analysis of data from clinical and community-based epidemiological/vaccine studies. His primary interests are to conduct researches on vaccines and infectious diseases. Currently, he is the Principal Investigator of several Flu, Tuberculosis, Oral polio, Hepatitis E, Japanese encephalitis, Pneumococcal and *Rotavirus* vaccine studies in ICDDR, B. He has received several awards and has more than 155 publications in international journals and had 120 conference presentations.

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