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Human Rotavirus vaccine: A decade of experience vaccinating infants worldwide

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Rotavirus gastroenteritis (RVGE) is a vaccine-preventable disease that confers a high medical and economic burden in both developed and developing countries. Rotarix® (GlaxoSmithKline) is an oral vaccine containing a G1P8 attenuated strain which was originally isolated from a male infant. This fully human rotavirus vaccine has shown to be efficacious for the prevention of severe RVGE in large-scale clinical trials involving over 100000 infants in both developed and less developed settings. Rotarix® has been licensed in more than 130 countries worldwide with more than 330 million doses delivered to date. Substantial reductions in morbidity and mortality related to RVGE and all-cause diarrhea have been reported worldwide following introduction of Rotarix® into childhood immunization programs. Broad protection against circulating strains is well-documented and currently there is no evidence of waning immunity in the 3 years following vaccination. There is increasing evidence that widespread vaccination with Rotarix® can result in herd protection, thereby enhancing the benefits of vaccination beyond the expected population based on trial data alone. This suggests that infants and young children who are too old or too young for vaccination or who may not be vaccinated for medical reasons can also benefit indirectly from universal mass vaccination. Estimates of vaccine effectiveness (VE) for Rotarix® against severe rotavirus gastro-enteritis (RVGE leading to hospitalization) range from 63% in Malawi to 92% in Taiwan, including high effectiveness rates in Belgium, Armenia, Moldavia, US, Australia and many more countries. VE has been demonstrated against rotavirus of both common (G1P[8], G2P[4], G3P[8] and G9P[8]) and less common (G9P[6] and G9P[4]) genotypes. These strains are circulating worldwide. Available data suggest that Rotarix® carries a small risk of intussusception within the week of vaccination. However, a recent meta-analysis showed a similar increased risk of intussusception during the first seven days after administration for both currently globally available RV vaccines; therefore, intussusception appears to be a 'class effect'. Available data confirm that the documented benefits of Rotarix® far outweigh any small temporal increase in risk for intussusception immediately following vaccination. 81 public health agencies worldwide strongly endorse routine RV vaccination of infants by 2016. The main challenge now is to increase RV vaccine use anywhere.

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