

# Multicenter Prospective Study of the Burden of Rotavirus Acute Gastroenteritis in Europe, 2004–2005: The REVEAL Study

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**Background.** Rotavirus is recognized as a significant cause of pediatric gastroenteritis worldwide. Comprehensive data on the burden of rotavirus disease in Europe were lacking.

**Methods.** A prospective, multicenter, observational study was conducted during the 2004–2005 season in selected areas of Belgium, France, Germany, Italy, Spain, Sweden, and the United Kingdom, to estimate the incidence of acute gastroenteritis (AGE) and rotavirus gastroenteritis (RVGE) in children <5 years of age seeking medical care in primary care, emergency department, and hospital settings.

**Results.** A total of 2846 children with AGE were included in the study, and, of the 2712 children for whom ELISA results were available, 1102 (40.6%) were found to be rotavirus positive. The estimated annual incidence of RVGE was 2.07–4.96 cases/100 children <5 years of age, and it was highest among children 6–23 months of age, with 56.7%–74.2% of all RVGE cases occurring in children in this age group. Overall, RVGE was estimated to account for 27.8%–52.0% of AGE cases, and it was responsible for up to two-thirds of hospitalizations and emergency department consultations, as well as one-third of primary care consultations for AGE.

**Conclusions.** Rotavirus infections account for a significant proportion of AGE cases in children <5 years of age in Europe, many of whom require frequent primary care consultations or care in emergency department and/or hospital settings. The results of the present study suggest that routine rotavirus vaccination for infants <6 months of age could significantly reduce the substantial burden of this potentially serious childhood disease.

Rotavirus is the most common cause of severe acute gastroenteritis (AGE) in young children worldwide [1–4]. Rotavirus gastroenteritis (RVGE) can lead to severe dehydration [2, 5], and, consequently, it is estimated that RVGE accounts for ~39% of all deaths due to diarrhea in children <5 years of age worldwide [6]. Although mortality rates associated with RVGE in industrialized countries are low, rotavirus is a significant cause of disease and hospitalization [2], with 1 in 54 children <5 years of age being hospitalized with RVGE in the European Union [7]. Rotavirus is also a frequent

cause of nosocomial infection in children who are hospitalized for reasons other than RVGE [8].

Rotavirus infections are most common in children 6–24 months of age [2, 5, 9]. Most children will have

Potential conflicts of interest: P.V.D. has been principal investigator of vaccine trials for Merck, Sanofi Pasteur MSD, and GlaxoSmithKline Biologicals, for which the University of Antwerp receives research grants. C.G. has an educational grant from and a consultation agreement with Sanofi Pasteur MSD, GlaxoSmithKline, Abbott, Roche, Tibotec, and Boehringer Ingelheim. L.G. has been principal investigator of vaccine trials for GlaxoSmithKline, Merck, Sanofi Pasteur MSD, Wyeth, and MedImmune. All other authors report no potential conflicts.

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<sup>a</sup> Further details of the REVEAL Study Group are provided after the text.

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