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Impact of rotavirus vaccination on childhood deaths from diarrhea in Brazil

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SUMMARY

Objectives: Rotavirus vaccination was introduced in Brazil in March 2006, targeting an annual birth cohort of approximately 3.5 million. We analyzed trends in all-cause gastroenteritis-related deaths in children <5 years of age during the pre- and post-vaccination periods.
Methods: Data from the National Immunization Program and the Mortality Information System were used to calculate vaccine coverage and mortality rates related to gastroenteritis in children <1 year and 1–4 years of age, using population estimates from the census as the denominator. Relative reductions in mortality rates were calculated for 2007 and 2008, using the 2004–2005 mean as baseline before vaccine introduction.
Results: Coverage of two doses of human rotavirus vaccine was 39% in 2006, increasing to 72% in 2007 and 77% in 2008. During 2004–2005, the gastroenteritis mortality rate in children <1 year of age was 56.9 per 100 000, decreasing by 30% (95% confidence interval (CI) 19–41) in 2007 and by 39% (95% CI 29–49) in 2008. In children 1–4 years of age, the mortality rate was 4.5 per 100 000 during 2004–2005, decreasing by 29% (95% CI 10–49) in 2007 and by 33% (95% CI 15–52) in 2008.
Conclusions: The decreased rates of childhood gastroenteritis-related deaths in Brazil following rotavirus vaccine introduction, particularly among children <1 year of age, suggest the potential benefit of vaccination.
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1. Introduction

Rotavirus infection remains the most common cause of severe, dehydrating gastroenteritis among children worldwide. Almost every child in the world, in both developed and developing countries, will be infected with rotavirus in the first 5 years of life. Approximately 611 000 childhood deaths annually are caused by rotavirus, most of them in developing countries.[1] Since only non-specific symptomatic therapies are available, prevention by vaccination is considered to be critical for effective control of rotavirus infection and may have a significant impact on the incidence of severe dehydrating rotavirus disease.[1]

With the widespread use of oral rehydration therapy strategies, deaths from diarrhea have declined substantially in the developing world. Diarrhea morbidity has not had a concomitant decrease, with an estimated 3–5 billion cases of diarrhea occurring worldwide each year, mostly among children.[2,3] In Brazil, declining trends in gastroenteritis-related mortality associated with the increased use of oral rehydration therapy were observed in the 1980s and 1990s.[4] Nonetheless, diarrhea remains an important cause of childhood morbidity and mortality, with rotavirus infections estimated to cause approximately 3.5 million diarrhea episodes, 655 853 outpatient visits, 92 453 hospitalizations, and 850 deaths each year in children aged ≤5 years, before vaccine introduction.[5]

Brazil was one of the first Latin American countries to include the human rotavirus vaccine into the expanded program on immunization in March 2006. A marked decline in the number of all-cause gastroenteritis hospitalizations among children aged <1 year was observed one year after vaccine introduction.[6–8] In this study, we analyzed the trends in all-cause gastroenteritis-related mortality among children aged <5 years in Brazil before and after implementation of rotavirus vaccination.

2. Methods

2.1. Vaccine coverage

The number of first and second doses of rotavirus vaccine administered are recorded at the local level by primary health care

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workers, entered into the National Immunization Program database at the municipal level and transmitted electronically to the state and national level. The numbers for both the first and second doses and vaccine coverage are available at the National Unified Health System Database (DATASUS) website and data can be tabulated by municipality, state, region, and year. From the year 2000, the National Immunization Program started using the number of live births as recorded in the Live Birth Information System (SINASC) for vaccine coverage calculations. Whereas the coverage of SINASC has increased from 75% (range 55–102) in 1994 to 92% (range 84–100) in 2006, underreporting of live births still occurs, with the lowest coverage in the Northeast region.[9] In addition, SINASC data used as the denominator for vaccine coverage calculations are generally from the birth cohort of the two previous years. In this study, we chose to use the census estimates for the population aged <1 year and 1–4 years to calculate rotavirus vaccine coverage for the first and second dose from 2006 to 2008, to estimate the cumulative proportion of children who had received rotavirus vaccination each year.

2.2. Mortality data

The Brazilian Ministry of Health is responsible for maintaining mortality data based on death certificates. The Mortality Information System (Sistema de Informação de Mortalidade – SIM) contains data for primary cause of death obtained from death certificates, and using the International Classification of Diseases (ICD), 10th Revision (since 1998). Data collected from death certificates are recorded and analyzed for consistency at the municipal level, transmitted electronically to the state and national level, and made available for direct tabulation on the DATASUS website. Annual databases usually take up to two years to be finalized. The coverage of the SIM is calculated based on the number of observed deaths (reported to the system) divided by the number of expected deaths (based on census projections) for all ages and for the age group <1 year. From 1991 to 2006, the coverage increased from 78% to 89% overall and from 56% to 72% in the age group <1 year. By 2006, the coverage had increased in all regions, reaching ≥85%, except the Northeast region, where only 54% of expected deaths in children <1 year were reported.[9]

We obtained data on all-cause gastroenteritis-related deaths among children <5 years of age during 1998–2008 from the Mortality Information System using the codes A00 to A09 of the ICD 10th Revision. Annual rates of all-cause gastroenteritis-related mortality were calculated using the population estimates from the census as a denominator. The mean rate of all-cause gastroenteritis-related mortality during 2004–2005 was used as baseline to compare with post-vaccination years 2007 and 2008. This baseline period was chosen because a declining trend was already in evidence for the past decades and would artificially increase the presumed impact of vaccination. We considered 2006 a transitional year and excluded it from the analysis because vaccination was introduced during this year and coverage was suboptimal. Analysis was stratified according to age groups <1 year and 1–4 years and by region. The absolute and relative reduction in deaths and mortality rate were calculated, with 95% confidence intervals.[10] Analysis was performed using SAS statistical software, version 9.1 and Microsoft Excel.

3. Results

3.1. Vaccine coverage

From March 2006 to December 2008, more than 13.5 million doses of human rotavirus vaccine were administered to children <1 year of age, 56% as first doses and 44% as second doses. Coverage of one dose of human rotavirus vaccine was 60% in 2006, 85% in 2007, and 90% in 2008. Lower vaccine coverage was observed for the second dose: 39% in 2006, 72% in 2007, and 77% in 2008. In 2008, an estimated 38% of the population 1–4 years of age had received one vaccine dose, with 28% having received two doses. Vaccine coverage varied by region, being highest in the South and Southeast regions, where the coverage of the second dose reached 88% and 84% in 2008, respectively, and remained the lowest in the North (66%) and Northeast (69%) regions. All regions achieved over 80% vaccine coverage for the first dose in 2008.

3.2. All-cause gastroenteritis-related mortality

Of 33 363 gastroenteritis-related deaths among children <5 years of age reported in Brazil during 1998–2008, 27 375 (82%) were in children <1 year of age. This age group has seen a marked decline in the number and rates of gastroenteritis-related deaths over the past decade (Fig. 1).

During 2004–2005, considered the baseline period before vaccine introduction, the mean number of gastroenteritis-related deaths observed in children <1 year was 1994 and in those aged 1–4 years was 516, of which 1185 (59%) and 231 (45%), respectively, occurred in the Northeast region. A reduction in the number of gastroenteritis-related deaths in children <1 year of age was observed in all regions in 2007 and 2008 (Fig. 2), by 36% (range 27–55) and 45% (range 37–64), respectively. The highest reduction rate in children <1 year of age was observed in the South region (54%) in 2008, whereas the absolute number of gastroenteritis-related deaths in the Northeast region fell from a mean of 1185 during 2004–2005 to 751 (by 37%) in 2007 and 661 (by 44%) in 2008. In children 1–4 years of age, gastroenteritis-related deaths decreased by 28% (range 15–48) in 2007 and by 34% (range 0–48) in 2008, with the highest reduction rates observed in the North and Mid-West regions.

The gastroenteritis-related mortality rate in children aged <1 year fell from a mean of 56.9 per 100 000 during 2004–2005, to 39.6 in 2007 and 35.0 in 2008, representing relative reductions of 30% (95% confidence interval (CI) 19–41) and 39% (95% CI 29–49), respectively. The highest mortality rates were observed in the Northeast region, with a mean of 112.4 per 100 000 during 2004–2005, decreasing by 35% (95% CI 29–41) in 2007 and by 42% (95% CI 37–48) in 2008 (Table 1). In children aged 1–4 years, the gastroenteritis mortality was 4.5 per 100 000 during 2004–2005, decreasing by 29% (95% CI 10–49) in 2007 and by 33% (95% CI 15–52) in 2008. The relative reduction in this age group was significant in both years only in the North and Mid-West regions (Table 1).

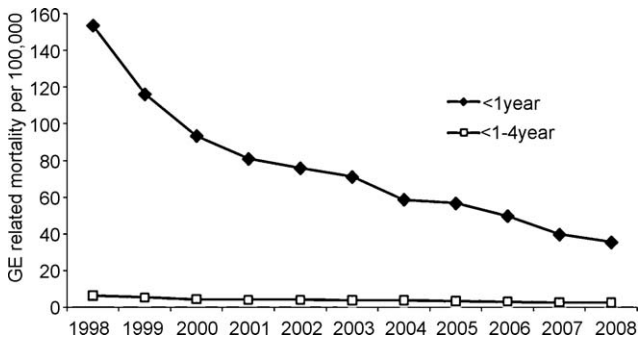

Fig. 1. Trends over time of gastroenteritis-related deaths by age group, Brazil, 1998–2008.

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