

INFLUENCE OF HUMAN ROTAVIRUS VACCINE IN HOSPITALIZATIONS FOR GASTROENTERITIS IN CHILDREN IN BRAZIL

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ABSTRACT

Objectives: to describe and analyze the influence of human rotavirus vaccine on hospitalizations for gastroenteritis in children under 5 years of age, in Brazil, 2001 to 2018 (pre- and post-vaccination period).

Method: this is a retrospective, descriptive ecological study, combining the description of a time series from 2001 to 2018 and collected in the months August 2019 to January 2020. The data were obtained from a secondary source. To analyze the effect of different variables, multiple models of mathematical evaluations were used (accumulated growth rate, geometric growth rate; standard deviation, mean, variance and simple linear regression). The level of significance was set at 5% ($p < 0.05$).

Results: there was a reduction in hospitalizations related to gastroenteritis in children under 5 years old, when comparing the pre- and post-vaccination periods. This reduction occurred in all Brazilian regions.

Conclusion: after the implementation of human rotavirus vaccine, there was a significant reduction in hospitalizations of children under 5 years.

DESCRIPTORS: Child. Vaccines. Rotavirus infections. Gastroenteritis. Hospitalization.

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INFLUÊNCIA DA VACINA CONTRA O ROTAVÍRUS HUMANO EM HOSPITALIZAÇÕES POR GASTROENTERITE EM CRIANÇAS NO BRASIL

RESUMO

Objetivos: descrever e analisar a influência da vacina contra o rotavírus humano nas hospitalizações por gastroenterite em crianças menores de 5 anos, no Brasil, 2001 a 2018 (período pré e pós-vacinal).

Método: trata-se de um estudo ecológico retrospectivo, descritivo, combinando a descrição das séries temporais do período de 2001 a 2018. Os dados foram obtidos de fonte secundária e coletados nos meses de agosto de 2019 a janeiro de 2020. Para análise do efeito de diferentes variáveis, utilizaram-se múltiplos modelos de avaliações matemáticas (taxa de crescimento acumulado, taxa de crescimento geométrico; desvio padrão, média, variância e regressão linear simples). Considerou-se o nível de significância de 5% ($p < 0,05$).

Resultados: houve redução das hospitalizações relacionadas à gastroenterites em crianças menores de 5 anos, quando comparados os períodos pré e pós-vacinal. Essa redução ocorreu em todas as regiões brasileiras.

Conclusão: após a implementação da vacina contra o rotavírus humano, houve expressiva redução das hospitalizações de crianças menores de 5 anos.

DESCRITORES: Criança. Vacinas. Infecções por rotavírus. Gastroenterite. Hospitalização.

INFLUENCIA DE LA VACUNA CONTRA EL ROTAVIRUS HUMANO EN LAS HOSPITALIZACIONES POR GASTROENTERITIS EN NIÑOS EN BRASIL

RESUMEN

Objetivos: describir y analizar la influencia de la vacuna contra el rotavirus humano en las hospitalizaciones por gastroenteritis en niños menores de 5 años, en Brasil, 2001 a 2018 (período pre y posvacunación).

Método: se trata de un estudio ecológico descriptivo, retrospectivo, que combina la descripción de la serie temporal de 2001 a 2018 y recogidos en los meses de 2019 a enero de 2020. Los datos se obtuvieron de una fuente secundaria. Para analizar el efecto de diferentes variables se utilizaron múltiples modelos de evaluaciones matemáticas (tasa de crecimiento acumulada, tasa de crecimiento geométrico; desviación estándar, media, varianza y regresión lineal simple). Se consideró el nivel de significancia del 5% ($p < 0,05$).

Resultados: hubo una reducción de las hospitalizaciones por gastroenteritis en menores de 5 años, al comparar los periodos pre y posvacunación. Esta reducción ocurrió en todas las regiones brasileñas.

Conclusión: luego de la implementación de la vacuna contra el rotavirus humano, hubo una reducción significativa en las hospitalizaciones de niños menores de 5 años.

DESCRIPTORES: Niño. Vacunas. Infecciones por rotavirus. Gastroenteritis. Hospitalización.

INTRODUCTION

Rotavirus belongs to the *Reoviridae* family, has a double strand of ribonucleic acid (RNA), can be transmitted via fecal-oral and through aerial propagation, and is often found in the feces of sick children¹.

The virus has seven groups (A to G), with only groups A, B and C being related to rotavirus infections in humans, and group A is responsible for 95% of the incidence in children. Among the rotaviruses of this group, different types of antigens (serotypes) are identified, based on the antigenic differences of the internal capsid proteins of VP7 glycoprotein (G) and VP4². It is known that the first rotavirus infection induces partial immunity against other serotypes, decreasing the symptoms of subsequent infections. Thus, rotavirus is known to be one of the most relevant viral agents among diseases considered to be diarrheal³.

The most common cause of diarrhea in children under five years of age worldwide, is caused by rotavirus, being responsible for approximately 600 thousand deaths per year and 40% of hospitalizations. In the American continent alone, there are an estimated 75,000 hospitalizations and 15,000 deaths annually. Rotavirus is considered ubiquitous and globally infects almost all children aged 3 to 5 years⁴.

According to the study "Epidemiology and Prevention of Vaccine-Preventable Diseases", from the Centers for Disease Control and Prevention (CDC), in the United States, children under the age of five are at greater risk of contracting and dying from rotavirus disease. It also points out that almost every child will have rotavirus infections at least once before the age of five, with the first infection usually occurring before the age of three. Other studies highlight that the rate of hospitalizations for rotavirus is variable in children under five years of age, depending on socioeconomic factors in the country⁵⁻⁶.

Considering the epidemiological importance of this pathogen and the impacts caused by it, translated by high rates of infant morbidity and mortality due to diarrhea, investments in research to provide an effective and safe vaccine against rotavirus have been carried out since 1980. In 1988 it was licensed, in the United States, the first rotavirus vaccine, which less than a year later, needed to be suspended due to the increased reporting of cases of intussusception in vaccinated children⁶⁻⁷. From this, several discussions arose among scholars, who sought an effective solution that could respond to the importance that the grievance assumed worldwide.

In Brazil, investigations began to be developed in the early 1990s. During this period, the researchers combined the safety, immunogenicity and effectiveness of three doses of a tetravalent vaccine capable of preventing diarrhea caused by the virus of the *Reoviridae* family, rotavirus disease. The oral human rotavirus vaccine (VORH) was licensed by the National Health Surveillance Agency (Anvisa) in June 2005, under the trade name Rotarix[®] from the Glaxo Smith Kline Biologicals laboratory⁵⁻⁷.

Following the proposal to continuously improve the actions of the Brazilian National Immunization Program, in March 2006, the rotavirus vaccine was inserted in the children's calendar, representing a wide advance in the country's health protection actions. It is an oral, attenuated, monovalent vaccine (G1P1A [8]), strain RIX4414, with high immunogenicity, efficacy and safety, being applied at the ages of 2 months (1st dose) and 4 months (2nd dose), following this scheme in the vaccination calendar provided by the Ministry of Health for the current year⁵⁻⁸.

The vaccine is available to the entire target population in Primary Health Care (PHC), that is, in Family Health Strategies (FHS), Basic Health Units (BHU) and Municipal Health Centers (MHC). Raising the awareness of the population or community to increase vaccination coverage and mobilize those responsible to immunize children, including VORH, is carried out mainly by nurses, nursing technicians and community health workers, whether in individual or collective guidelines.

According to studies with infants aged 6 to 13 weeks, from 11 countries in Latin America, including Brazil (Belém/PA), the Rotarix[®] vaccine was effective between 84.7% and 85% in preventing

severe diarrhea in need of hospitalization. The efficacy for preventing severe diarrhea for all serotypes in group G was 91.8%, for serotypes G3P [8], G4P [8] and G9P [8] was 87.3% and for serotype G2P [4] was 41.0%. Protection started about two weeks after the second dose⁷⁻⁹.

VORH has been recommended by the World Health Organization (WHO) for use in 89 countries on all continents, and since 2009 a worldwide sentinel surveillance network for invasive bacterial diseases and rotavirus has been established¹⁰⁻¹². The potential positive impact of including VORH in reducing child mortality - one of the indicators that reflect the level of development in a country, can be analyzed by the relationship between vaccination and hospitalization¹³⁻¹⁶.

This article aims to describe and analyze the influence of human rotavirus vaccine on the rate of hospitalizations for gastroenteritis in children under 5 years of age, in Brazil, between 2001 and 2018, which comprises the pre- and post-implantation period of VORH in the vaccination calendar.

METHOD

This is a retrospective, descriptive ecological study, combining the description of the time series from 2001 to 2018 (pre- and post-vaccination period). The units of analysis of the investigation were hospital admissions for rotavirus/coverage of the human rotavirus vaccine in the population group of children (<5 years), aggregated according to the year of occurrence of the event and region of residence in Brazil. Data were collected from August 2019 to January 2020. As a tool for methodological guidance, Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) was used¹⁷.

The study population consisted of cases of hospitalization of children under the age of five for rotavirus infections. The characterization of the information collected, according to its source, was described as follows: I - Unified Health System Hospital Information System (HIS/SUS (*Sistema Único de Saúde*)), DATASUS (Hospitalization in children under 5 years old by region of residence; Length of hospital stay in children aged 0 to 4 years for rotavirus infections); II - Brazilian National Immunization Program Information System (SIPNI - *Sistema de Informação do Programa Nacional de Imunização*), DATASUS (Human rotavirus vaccine coverage; Human rotavirus vaccine doses applied); III - Brazilian Institute of Geography and Statistics (Population by region; Gross domestic product by region).

The specific causes of hospitalization of interest were obtained from SIH/SUS, described as the main and secondary diagnosis. As outcomes, morbidity and mortality rates were considered. The comparison of variables was performed in descriptive and analytical terms, according to pre-vaccination versus post-vaccination period; pre-vaccination period versus vaccination coverage rate; and post-vaccination period versus vaccination coverage rate.

To analyze the effect of different variables, simple linear regression models, accumulated growth rate, geometric growth rate, mean, Pearson's correlation test, standard deviation and variance, as well as geospatial distribution of the number of doses of human rotavirus vaccine applied.

The level of significance was set at 5% ($p < 0.05$) for the identification of statistically significant independent variables. Linear regression models were also used to correct possible failures in the probability distribution. Microsoft Office Excel, version 2019, GraphPad Prism 5.0 and QGIS 3.4.8 were used.

This study collected secondary administrative data obtained from the public domain SIH/SUS databases, released by the Ministry of Health of Brazil, and, therefore, dispensed with appreciation by the Institutional Review Board, according to Resolution 466/2012 of the Brazilian National Health Council (*Conselho Nacional de Saúde*) and similar national and international legislation. The information was used exclusively for the purposes of this study and the information, elaborated and presented collectively, in such a way that none of the results referred to a nominal individual, nor did it imply any damage to the individuals or institutions involved.

RESULTS

In population terms, there was a growth trend in the Northeast, Southeast, South and Center-West regions, only in the North there was a reduction in the growth rate. In contrast to the reduction in population growth in the North, coverage for the rotavirus vaccine in that region has increased by 142% since the vaccine was implanted in 2006, as shown in Table 1.

There was a significant reduction in hospital admissions related to diarrhea and gastroenteritis in children under 5 years of age in all Brazilian regions in the pre- and post-vaccination period, as shown in Table 2. Almost all regions reduced hospitalizations for diarrhea and gastroenteritis by 50% after the vaccination period. When Pearson's correlation test was applied, a strong correlation was observed.

Following the same line as hospital admissions, deaths due to diarrhea and gastroenteritis in children under 5 years of age decreased significantly, as shown in Table 3. Pearson's test showed a strong correlation regarding the pre- and post-vaccination period.

Table 1 – Time trend of population growth and coverage of rotavirus vaccine from 2006 to 2018. Rio de Janeiro, RJ, Brazil, 2020.

Region	General population				Vaccination coverage			
	AGR *	GGR [†]	Mean	SD [‡]	AGR *	GGR [†]	Mean	SD [‡]
North	-89.6%	-24.6%	34,754,861.1	49,541,469.4	142%	8%	71.2	13.1
Northeast	6.9%	0.8%	55,550,999.2	1,517,482	120%	7%	81.1	12.8
Southeast	9.2%	1.1%	84,360.072	2,576,444.3	63%	4%	88.3	10.3
South	8.7%	1%	28,728,856.1	875,300.7	78%	5%	87.3	11.7
Center-West	14.5%	1.7%	15,110,699.4	692,960.6	113%	7%	87.6	14.4

Source: DATASUS. * AGR: accumulated growth rate; [†]GGR: geometric growth rate; [‡]SD: standard deviation.

Table 2 – Hospitalizations for diarrhea and gastroenteritis in children under 5 years of age in the pre-vaccination period (2001 to 2006) and post-vaccination period (2007 to 2018). Rio de Janeiro, RJ, Brazil, 2020.

Region	Pre-vaccination period			Post-vaccination period			Pearson's p
	Mean	SD*	Variance	Mean	SD*	Variance	
North	16,958.4	1,783.8	1,181,835.8%	15,629.6	2,562.5	6,566,331.9%	
Northeast	55,696.2	2,334.4	5,449,499%	32,390.4	11,447.8	131,051,065%	
Southeast	32,148.8	2,229.3	4,969,713%	14,823.4	4,482.2	20,089,736.2%	1
South	7,473.6	623.3	388,469%	5,193.2	1,749.2	3,059,673.3%	
Center-West	9,922.6	1,083.6	1,174,114.6%	5,457.2	2,134.9	4,557,698.2%	

Source: DATASUS: * SD: standard deviation.

Table 3 – Deaths due to diarrhea and gastroenteritis in children under 5 years old in the pre-vaccination period (2001 to 2005) and post-vaccination period (2006 to 2018). Rio de Janeiro, RJ, Brazil, 2020.

Region	Pre-vaccination period			Post-vaccination period			Pearson's p
	Mean	SD*	Variance	Mean	SD*	Variance	
North	336.8	20.6	423%	182.9	47.5	2,252.7%	
Northeast	1,503.4	137.8	18,986.2%	452.8	304	92,390%	
Southeast	423.2	76.5	5,851.8%	147.9	56	3,136.8%	1
South	137.4	27.9	777%	37.5	16	257%	
Center-West	174.8	15.6	243.4%	76.5	25.9	672.2%	

Source: DATASUS. *SD: Standard Deviation.

Figure 1 shows the simple linear regression test that highlights the existence of a positive correlation (C, F) between the mean rate of vaccination coverage versus mean rate of deaths versus mean rate of hospitalizations for diarrhea and gastroenteritis in children under 5 years old.

Figure 2 shows the states with the best and worst performance in terms of the number of doses of rotavirus vaccine applied from 2006 to 2018. Analysis was performed considering the proportion between population/doses applied. It should be noted that the State of Roraima had the best national performance in terms of the number of doses applied for the rotavirus vaccine. As a result of meeting vaccination targets, the state has reported the lowest death rates from diarrhea and gastroenteritis in children under five. Against the data from Roraima, Rio Grande do Sul, followed by Bahia, present the worst statistics in the number of doses applied for the rotavirus vaccine from 2006 to 2018.

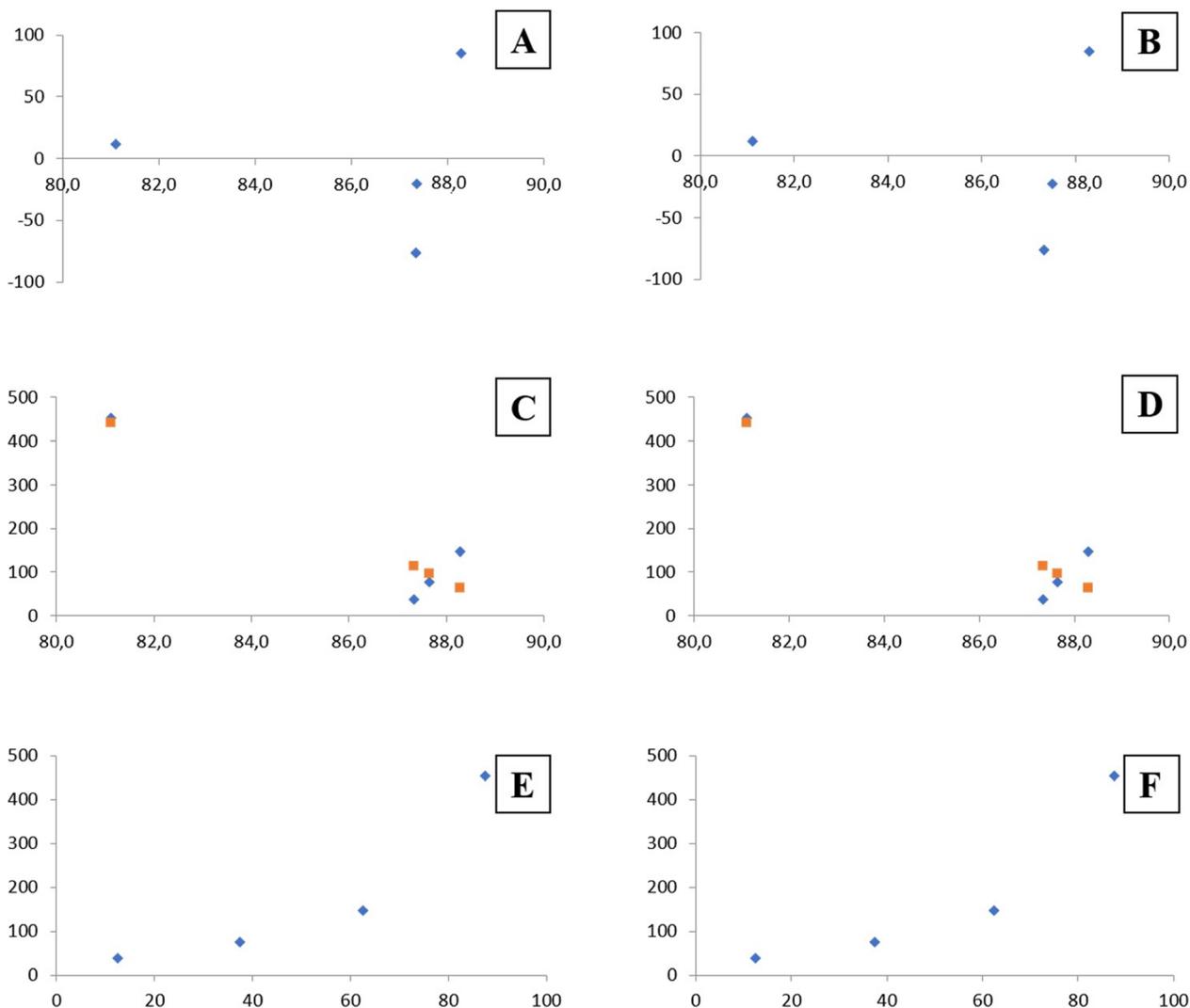


Figure 1 – Simple linear regression of the mean rate of vaccination coverage versus mean rate of deaths (A, B, C) versus mean rate of hospitalizations (D, E, F) due to diarrhea and gastroenteritis in children under 5 years old. Plot of normal probability (AD); Waste plotting (BE); Line adjustment plot (CF). Rio de Janeiro, RJ, Brazil, 2020.

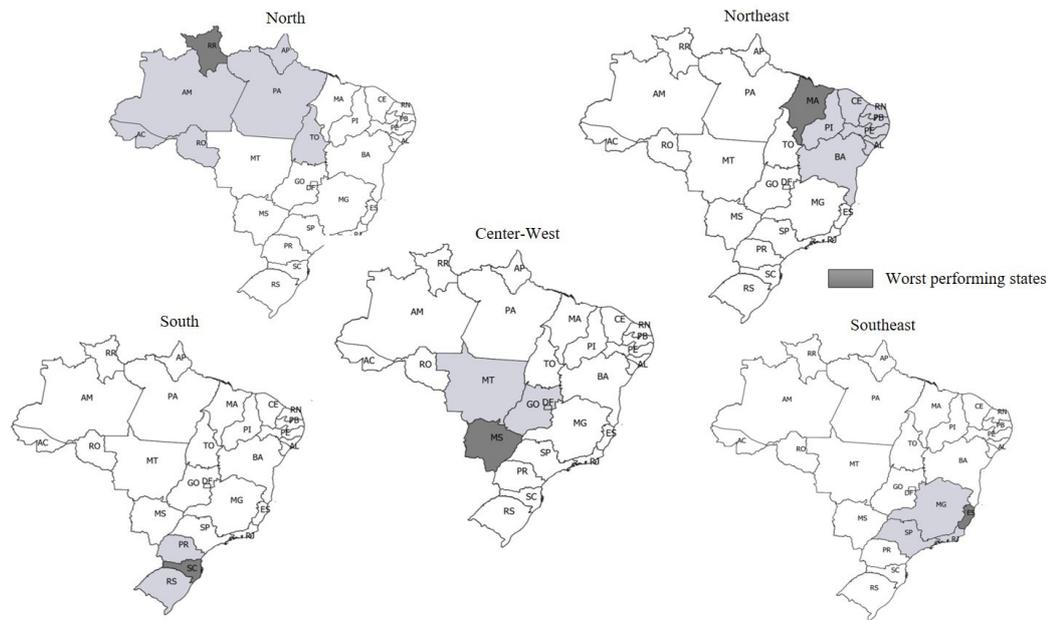
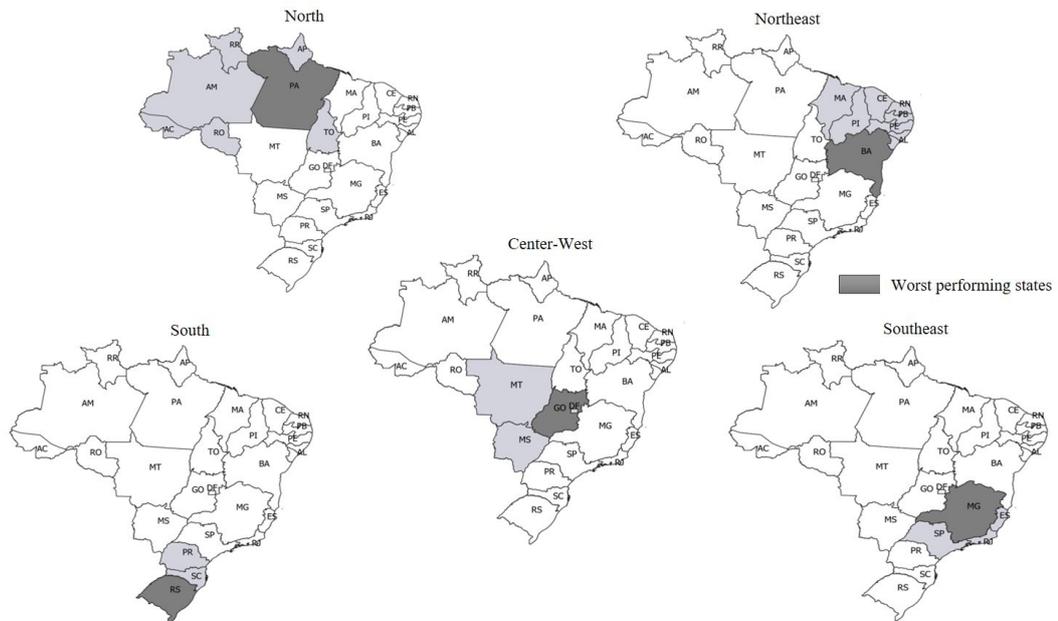
A**B**

Figure 2 – A) Geospatial distribution (by region/state) of the number of rotavirus vaccine doses applied to children under 5 years old, from 2006 to 2018, proportional to the population of each unit of the federation; **B)** Geospatial distribution (by region/state) of the number of doses of rotavirus vaccine applied to children under 5 years old, from 2006 to 2018, proportional to the population of each unit of the federation. Rio de Janeiro, RJ, Brazil, 2020.

DISCUSSION

Since the introduction of VORH, in 2006, in the Child Vaccine Calendar, coverage rates have been increasing over the years. However, there are still factors that make it impossible to take the vaccine in a timely and effective way¹⁴.

The Ministry of Health has warned of a reduction in vaccination coverage in the country, with pockets of low coverage being even more worrying¹⁸. However, analysis of the period shows that since the introduction of VORH, in 2006, in the infant vaccination calendar, coverage rates have been increasing over the years.

A study with school children in the city of Natal/RN, found that 22% of vaccination cards analyzed were incomplete and/or had no record of any dose of the vaccine. The main factors identified as barriers to achieving full coverage were: family resistance to vaccines, fear of adverse reactions, insecurity in the concomitant administration of a high quantity of vaccines, as well as the lack of opportunity for health services to vaccination activity¹³.

The effects of increased vaccination coverage against rotavirus, as identified by the results of this study, point out that in the post-vaccination period (after the implementation of VORH in the calendar) there was a reduction in hospital admissions of children under five years of age for diarrhea and gastroenteritis, these quantities being inversely proportional. As more children are vaccinated, the chances of hospitalization for these causes decrease, as pointed out in other studies¹⁴⁻¹⁶.

A study carried out in Paraná identified that after the introduction of VORH vaccine, hospitalization rates decreased in relation to the pre-vaccination period, representing a 30% reduction in hospitalizations in children under one year of age. The probability of hospitalization also decreased at other ages (<5 years), presenting a 17% reduction after vaccination, which also directly impacts the costs and expenses of hospitalization to the Brazilian health system⁴.

In addition to the reduction in hospitalizations, a Brazilian study shows a decline in mortality rates in children aged up to five years, in the first three years (2007-2009) after the inclusion of oral rotavirus vaccine, with a greater impact in those younger than two years (reduction of 28%), corroborating the results of this study⁴.

It was possible to observe an increase in the coverage rate of VORH vaccine in all states in the country in the last 12 years, with the North, Northeast and Center-West Regions standing out in this context. The Northeast was the one that stood out the most in the construction of the inversely proportional relationship of increased vaccination coverage followed by a drop in hospital admissions for diarrhea and gastroenteritis in the population studied. This result corroborates with studies that identified a reduction in regional inequalities through the guarantee and offer of services.

The positive influence of VORH in reducing hospitalizations - which also impacts on reducing child mortality - highlights the need for continuous adoption of protective actions and strengthening of PHC network. At this point in the health care networks, families are sensitized and oriented about the importance of adhering to the child's vaccination schedule, in addition to ensuring the immunobiological. The recent changes in the logic of assistance, as well as in the broader policies of Primary Care in Brazil, may compromise the viability of both the immunization program and the actions of raising the population's awareness of the importance of specific prevention through vaccines. It is up to professionals to recognize the need for this mutual strengthening of actions¹⁹.

Finally, it is understood that the elements related to the robustness of primary health care include, since the increase in funding in the area, incentives for research mainly in actions that meet the demand for the prevention of diseases in health, the training of professionals until the inspection of the cold chain and maintenance of immunobiologicals in BHU²⁰⁻²³.

The main limitation concerns the nature of the data, since it is secondary data and, therefore, subject to possible errors related to data filling and registration, in addition to underreporting by the municipalities/states, situations that are not subject to be handled by the researchers.

CONCLUSION

The data from this study demonstrated that the use of human rotavirus vaccine directly influenced the reduction of hospital admissions related to diarrhea and gastroenteritis and deaths due to the same cause in children under 5 years of age in all Brazilian regions. These data reinforce a worldwide trend, when considering the vaccine application as a form of immunization against rotavirus. For Brazil, these results reiterate the need to guarantee and expand vaccination coverage as a strategy to ensure less morbidity and mortality from preventable causes, especially among children.

It is recommended to continue studies on the topic, since identifying and measuring variables on the expected results of immunization, but also collaborating in the inclusion of inputs, technologies and services to be offered by SUS.

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NOTES

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