# Reduction in Gastroenteritis With the Use of Pentavalent Rotavirus Vaccine in a Primary Practice

**WHAT'S KNOWN ON THIS SUBJECT:** Increased use of the recently licensed RV5 has been associated with a significant decrease in the number of hospitalizations as a result of RV AGE.

**WHAT THIS STUDY ADDS:** Increased use of RV5 in a pediatric practice (40%–46%) was also associated with fewer all-cause AGE office visits (23%). The reduction was 27% for young children who were targeted for immunization and 18% for older groups, suggesting a herd-immunity effect.

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**KEY WORDS**

gastroenteritis, pediatrics, primary health care, public health, rotavirus vaccines

**ABBREVIATIONS**

RV—rotavirus
AGE—acute gastroenteritis
RV5—pentavalent rotavirus vaccine
ED—emergency department
CI—confidence interval
CHMPC—Children's Hospital Medical Practice Corporation
CHNO—Children's Hospital, New Orleans
OR—odds ratio

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## abstract

**OBJECTIVES:** Pentavalent rotavirus (RV) vaccine (RV5) was licensed in 2006 and recommended for routine childhood immunization. A significant decrease in the number of RV hospitalizations has been described. The objective of this study was to evaluate the effect of RV5 on acute gastroenteritis (AGE) seen in a primary practice.

**METHODS:** In July 2004, surveillance was initiated among children who were younger than 5 years and seen in a large pediatric practice in New Orleans for those who presented AGE, as determined by *International Classification of Diseases, Ninth Revision* codes. Primary care physician office visits, emergency department visits, and hospital admissions were identified by review of records. RV testing was performed only on those who were seen at the hospital.

**RESULTS:** Approximately 16 000 children who were younger than 5 years were followed in the practice during each year. For 2006–2007, 2007–2008, and 2008–2009, 11.1%, 40.3%, and 45.6% of age-eligible children, respectively, received ≥1 dose of RV5. As compared with 2004–2005 (before RV5), in 2007–2009, there was a significant decrease in all-cause AGE office visits (23%) and hospitalizations (50%). RV-positive cases (emergency department visits or hospitalizations) decreased by 67%. The decrease in RV-positive cases was more evident among children who were younger than 2 years (81%), with a strong trend among those who were aged 2 to <5 years (41%).

**CONCLUSIONS:** Increased use of RV5 in a pediatric practice was associated with fewer AGE office visits and hospitalizations. The reduction was specific for RV-positive AGE and seen among children who were targeted for immunization as well as older groups, suggesting a herd-immunity effect. *Pediatrics* 2010;126:e40–e45

Rotavirus (RV) infection is the main cause of severe, dehydrating acute gastroenteritis (AGE) in infants and young children worldwide. In the United States, in the prevaccine era, RV was responsible for >2.7 million cases of diarrhea, 410 000 office visits, 205 000 to 272 000 emergency department (ED) visits, 55 000 to 70 000 hospitalizations and 20 to 60 deaths every year, translating into $1 billion in direct medical and indirect expenses.[1,2] Because of the significant human and economic burden associated with the disease, it has been a priority to develop a vaccine to protect against RV.[3] Two RV vaccines have been licensed in the United States: in 2006, a pentavalent rotavirus vaccine (RV5; Rota Teq [Merck & Co, Inc, Whitehouse, NJ]), and in 2008 a monovalent rotavirus vaccine (RV1; Rotarix [GlaxoSmithKline, Brentford, Middlesex, United Kingdom]). In prelicensure studies, both vaccines showed excellent safety and efficacy profiles,[4] and current recommendations encourage the use of either product.[1,5] For RV5, in particular, its efficacy to prevent RV-AGE was reported as 74% (95% confidence interval [CI]: 67%–80%) for all cases, 86% (95% CI: 74%–92%) for office visits, and 96% (95% CI: 90%–98%) for hospitalizations; and use of RV5 was associated with 59% (95% CI: 52%–65%) reduction in hospitalizations as a result of diarrhea by any cause.[1,6]

Soon after the introduction of RV5 in 2006, the Centers for Disease Control and Prevention (Atlanta, GA) reported that for the 2007–2008 season, there was a dramatic decline and delay in the RV season concomitant with the increased use of the vaccine nationwide.[7,8] Similar findings were noted in a number of abstract reports at the 2008 annual meeting of the Infectious Diseases Society of America and a recent publication from the Children's Hospital of Philadelphia.[9] All of these postlicensure reports[7–9] concerned the use of RV5 because that was the only RV vaccine available during the evaluated time frame, and they confirmed the impact of RV5 on RV hospitalization (ie, the most severe cases). Our group has been interested in the impact of RV5 on the overall burden of RV in health care use: not only hospitalization but also outpatient office visits from a primary pediatric practice point of view. Because RV-AGE represents only a fraction (29%–37%) of all outpatient AGE visits,[10,11] it was not clear how much use of RV vaccine would affect the overall AGE rates. Here, we report our experience with those parameters for the first 3 years of use of RV5.

## METHODS

### Surveillance Site

Surveillance was conducted in the population attended by the Children's Hospital Medical Practice Corporation (CHMPC), a group of 38 pediatricians who practice in 14 locations in 5 parishes (counties) around the New Orleans area. CHMPC has a large patient base that is representative of different sectors and sociodemographic populations: ~17% of the children are served at an inner-city location, and 83% are served at a suburban location; 46% are covered by Medicaid, 51% are covered by private insurance, and 3% are self-pay. Information is continuously entered in a searchable database that contains information for each encounter. CHMPC providers advise patients to use Children's Hospital, New Orleans (CHNO) for ED visits and hospitalizations. In case of such a visit, CHMPC providers are contacted and follow-up at CHMPC or inpatient is arranged. Seasonality of RV in the area has year-to-year variability. Review of CHNO's laboratory records showed that in the 5 years before this surveillance, the RV season had started between November and February, lasted 4 to 5 months, and ended between March and May.

### Data Collection

Surveillance started in July 2004. Each surveillance year spanned from July 1 to June 30 the next year. At the end of each period, we obtained a copy of CHMPC's database for the cycle and reviewed the visit records to determine the number of patients who were younger than 5 years and were seen by CHMPC. When a record that a child had been seen (either for a well or sick visit) at least once during the season was found in the database, he or she was considered as under observation for the entire season; otherwise, he or she was not counted. Data were also collected on the number who received ≥1 dose of RV5 (CHMPC has used RV5 as the RV vaccine exclusively since mid-2006). We performed an audit of 200 randomly selected CHMPC's database immunization entries (100 RV5 recipients and 100 nonrecipients) to determine accuracy of the database as compared with the source clinical chart. Finally, AGE episodes were extracted from the database. AGE episodes were identified by the following *International Classification of Diseases, Ninth Revision* codes (any location) that are commonly used at CHMPC and their descriptor: 008.61 (RV), 008.8 (viral enteritis), 276.5 (dehydration), 787.01 (nausea with vomiting), 787.03 (vomiting alone), and 787.91 (diarrhea). The records at CHNO's laboratory were then reviewed to identify patients who were younger than 5 years in CHMPC's database and had been seen in the ED or hospitalized and had their stool tested for RV. Hospital-acquired infections (ie, those evident >3 days after admission) were excluded. RV testing was conducted by an enzyme immune assay (Rotaclone [Meridian Diagnostics, Cincinnati, OH]) and was done only for pa-

tients who were seen at CHNO (either the ED or hospitalized), not for those who were seen at CHMPC alone.

### Human Subject Research

Protocol review, approval, and oversight were provided by the institutional review board of Louisiana State University Health Sciences Center and CHNO.

### Statistical Analysis

Rates were calculated as number of events (AGE, RV-AGE) observed divided by the number of children (× 1000) who were seen at CHMPC for that given year. RV5 use was estimated by dividing the number of children who received ≥1 dose of RV5 by the number of children who were eligible by age to receive RV5 (× 100) from the time RV5 was made available to CHMPC and up to the month before start of the respective RV season (defined as the month when ≥10% of stool specimens tested positive for RV). On the basis of RV positivity detected at CHNO's laboratory, RV season for the years 2004–2005, 2005–2006, 2006–2007, 2007–2008, and 2008–2009 started in February, January, December, April, and October, respectively. Epi-Info's Statcalc program (EpiInfo 3.5 [Centers for Disease Control and Prevention, Atlanta, GA]) was used to calculate odds ratios (ORs) and 95% CIs. Percentage change in AGE activity was calculated as [1 − OR] × 100%.

## RESULTS

### Study Population

Five surveillance years, spanning the period 2004 to 2009, are included. In 2005–2006, Hurricane Katrina affected the area (landfall on August 29, 2005), forcing most offices to close and displacing the population, so the validity of surveillance for that year, we believe, is less reliable than for the other 4 years. Approximately 16 000 children who were younger than 5 years were seen by CHMPC providers each year; of them, ~6000 were younger than 1 year. There was a 10% drop in the number of children who were younger than 1 year and seen during 2005–2006, but the number soon increased. The annual number of total visits per child varied between 5.8 in those who were younger than 1 year to 2.5 in those aged 4 years. We estimate that ~22% of children were lost to follow-up each year.

### RV5 Vaccination

RV5 was first used in CHMPC in August 2006, so, for the first 2 years (2004–2005 and 2005–2006), no children under CHMPC's care received the vaccine. For 2006–2007, 2007–2008, and 2008–2009, ~11.1% (349 of 3137), 40.3% (3697 of 9163), and 45.6% (5133 of 11 262) of age-eligible children received ≥1 dose of RV5 before the start of the corresponding RV season. Audit of 200 randomly selected records showed that in 40 (20%) cases, there was a discrepancy between the database information and the source clinical record in terms of RV5 administration: in 22 (11%), a vaccine dose was given at an outside location, and in 18 (9%), the dose was given at CHMPC but not recorded in the database. In 18 (9%) of the cases, the discordance resulted in a misclassification of the child as unvaccinated when indeed he or she had received ≥1 dose of RV5.

### AGE Activity

Table 1 shows AGE activity expressed as total number of episodes and rate per 1000 children for each year. Before 2007–2008, ~13% of children were seen with AGE (all causes included), 93% at the doctor's office and 7% in the hospital; of these 7%, more than one-half (73%) were hospitalized. Also before 2007–2008, RV accounted for 21.8% of patients who had AGE and were seen in the ED and 38.1% of those who were hospitalized. Because RV testing was not performed at the office, that proportion cannot be determined. The numbers for 2005–2006—the year Hurricane Katrina affected the area—were lower than for the other 4 seasons, so the event resulted in a smaller surveillance population and less use of medical services.

### Time Trends of AGE Activity

Because surveillance was unreliable during 2005–2006, analyses ignore that year to estimate the effect that progressive introduction of RV5 had in AGE. In Table 1, the AGE rates for 2004–2005 are used as reference to compare to the respective rates for 2006–2007, 2007–2008, and 2008–2009 (as age-eligible children are increasingly vaccinated) and expressed as the OR (95% CI). During 2007–2008 and 2008–2009 (when RV vaccination was 40% and 46%, respectively), a significant decrease was noted in the rate of all-cause AGE episodes detected (20% and 28%, respectively), be it office visits (18% and 27%, respectively) or hospitalizations (50% and 50%, respectively). For 2006–2007 (when RV vaccination was 11%), the decreasing trends were similar but on a lower scale and noted mainly among patients who were hospitalized (28%). Testing for RV cause was frequent and increased over the years from 85% (for 2004–2005) and 81% (for 2005–2006) up to 94% (for 2008–2009). As shown in Table 1, there was no change in the rate of RV-negative cases detected during the 5 surveillance years, but in 2007–2008 and 2008–2009, there was a significant decrease in the rate of RV-positive cases (85% and 50%, respectively).

### AGE Activity by Age Group

Table 2 compares the combined AGE activity seen in 2007–2008 and 2008–

**TABLE 1** AGE Episodes Detected in the Study Population During the 5 Surveillance Years and Grouped by Setting and by Cause

| Parameter | Surveillance Year | | | | |
|---|---|---|---|---|---|
| | 2004–2005 | 2005–2006 | 2006–2007 | 2007–2008 | 2008–2009 |
| Total no. of children <5 y | 15 645 | 15 310 | 16 615 | 16 690 | 17 626 |
| AGE, all episodes | 2357 | 1735 | 2344 | 2077 | 1993 |
| Rate (per 1000 children) | 150.66 | 113.32 | 141.08 | 124.45 | 113.07 |
| OR (95% CI) | Reference | NA | 0.93 (0.87–0.99)[a] | 0.80 (0.75–0.85)[a] | 0.72 (0.67–0.77)[a] |
| AGE by setting | | | | | |
| Office visits | 2167 | 1628 | 2178 | 1938 | 1852 |
| Rate (per 1000 children) | 138.51 | 106.34 | 131.09 | 116.12 | 105.07 |
| OR (95% CI) | Reference | NA | 0.94 (0.88–1.00) | 0.82 (0.76–0.87)[a] | 0.73 (0.68–0.78)[a] |
| ED | 42 | 30 | 52 | 60 | 58 |
| Rate (per 1000 children) | 2.68 | 1.96 | 3.13 | 3.59 | 3.29 |
| OR (95% CI) | Reference | NA | 1.17 (0.76–1.79) | 1.34 (0.89–2.03) | 1.23 (0.81–1.86) |
| Hospitalizations | 148 | 77 | 114 | 79 | 83 |
| Rate (per 1000 children) | 9.46 | 5.03 | 6.86 | 4.73 | 4.71 |
| OR (95% CI) | Reference | NA | 0.72 (0.56–0.93)[a] | 0.50 (0.38–0.66)[a] | 0.50 (0.37–0.65)[a] |
| AGE by cause[b] | | | | | |
| RV-negative | 107 | 59 | 98 | 115 | 102 |
| Rate (per 1000 children) | 6.84 | 3.85 | 5.90 | 6.89 | 5.79 |
| OR (95% CI) | Reference | NA | 0.86 (0.65–1.14) | 1.01 (0.77–1.32) | 0.85 (0.64–1.12) |
| RV-positive | 55 | 28 | 47 | 9 | 31 |
| Rate (per 1000 children) | 3.52 | 1.83 | 2.83 | 0.54 | 1.76 |
| OR (95% CI) | Reference | NA | 0.80 (0.53–1.21) | 0.15 (0.07–0.32)[a] | 0.50 (0.31–0.79)[a] |
| Not tested | 28 | 20 | 21 | 15 | 8 |
| Rate (per 1000 children) | 1.79 | 1.31 | 1.26 | 0.90 | 0.45 |
| OR (95% CI) | Reference | NA | 0.71 (0.39–1.28) | 0.50 (0.26–0.97)[a] | 0.25 (0.11–0.58)[a] |

[a] Statistically significant.
[b] Includes ED visits and hospitalizations.

**TABLE 2** AGE, According to Age Group

| Parameter | Age Group | | | All Groups |
|---|---|---|---|---|
| | <1 y | 1 to <2 y | 2 to <5 y | |
| No. of children | | | | |
| 2004–2005 | 5559 | 2709 | 7377 | 15 645 |
| 2007–2009 | 12 889 | 5747 | 15 680 | 34 316 |
| AGE, office visits | | | | |
| 2004–2005[a] | 636 (114.4) | 629 (232.2) | 902 (122.3) | 2167 (138.5) |
| 2007–2009[a] | 1078 (83.6) | 1102 (191.8) | 1610 (102.7) | 3790 (110.4) |
| OR (95% CI) | 0.71 (0.64–0.78)[b] | 0.78 (0.70–0.88)[b] | 0.82 (0.75–0.90)[b] | 0.77 (0.73–0.82)[b] |
| AGE, hospitalizations | | | | |
| 2004–2005[a] | 66 (11.87) | 38 (14.03) | 44 (5.96) | 148 (9.46) |
| 2007–2009[a] | 79 (6.13) | 37 (6.44) | 46 (2.93) | 162 (4.72) |
| OR (95% CI) | 0.51 (0.37–0.72)[b] | 0.46 (0.28–0.73)[b] | 0.49 (0.32–0.76)[b] | 0.50 (0.39–0.62)[b] |
| AGE, RV-positive[c] | | | | |
| 2004–2005[a] | 14 (2.52) | 21 (7.75) | 20 (2.71) | 55 (3.52) |
| 2007–2009[a] | 5 (0.39) | 10 (1.74) | 25 (1.59) | 40 (1.17) |
| OR (95% CI) | 0.15 (0.05–0.46)[b] | 0.22 (0.10–0.50)[b] | 0.59 (0.31–1.10) | 0.33 (0.22–0.51)[b] |

[a] Number of events (rate per 1000 children).
[b] Statistically significant.
[c] Includes ED visits and hospitalizations.

2009 (when 40%–46% of age-eligible children received RV5) with 2004–2005 (before RV5) for age subgroups. As expressed by the OR, there was a significant—or close to significant—decrease in the various categories of AGE for all subgroups. In particular, for documented RV-positive AGE cases (either ED visits or hospitalizations), the decrease was more pronounced and statistically significant in the group of younger children (<1 year: 85%; 1 to <2 years: 78%) and close to significant for older children (2 to <5 years: 41%).

## RV Infection and Vaccination Status

Of the 170 cases of RV-positive diarrhea detected, 42 corresponded to children who were age-eligible to receive RV5; of them, 2 (4.8%) had documentation of having received the vaccine before the time of infection. Neither of these 2 children received the complete 3-dose vaccine series. One child received a single vaccine dose (RV infection 6 months after vaccination), and the other child received 2 doses of the vaccine (RV infection 16 months after vaccination). In contrast, of the 481 cases of RV-negative diarrhea, 218 were among RV5 age-eligible children; of them, 68 (31.2%) had received at least 1 dose of RV5 (25 received 1 dose, 22 received 2 doses, and 21 received 3 doses) before the episode of diarrhea. Hence, having received RV5 was more common among RV-negative than RV-positive cases ($\chi^2$ Yates corrected, $P = .0008$).

## DISCUSSION

Our study aimed to assess the impact of RV5 on health care use from a primary practice perspective. Others[7–9] have described that use of RV5 has led to a decrease in RV hospitalizations—the type of RV illness most affected by the vaccine.[1,6]—but most AGE cases that are brought to the attention of medical care—including those that are caused RV infection—do not result in hospitalization, and they are treated in an outpatient setting instead.[12] Because AGE is common among children, these are not trivial numbers, resulting in heavy use of medical services and work time lost by the parents.[2,13] So, from the physicians', third-party payers', and parents' perspective, a good vaccine would be 1 that decreases not only hospitalizations but also the overall number of AGE outpatient visits.

Similar to what has been described nationally,[7,8] our hospital noted a decrease (85%) and delay in the onset of the 2007–2008 RV season (starting in April instead of the usual November to February), but the subsequent season (2008–2009) saw an early start (October) and increased activity (approximately threefold higher than in 2007–2008). Part of the increase may have been attributable to increased detection (because fewer specimens were untested), and part may have been attributable to yearly variation in RV activity. Regardless, the RV activity level for 2008–2009 was still lower (50%) than prevaccine years. A national surveillance system also detected an increased in RV-positive results by laboratories in the South and Midwest for 2008–2009, as compared with 2007–2008.[14] These findings illustrate the highly dynamic process of RV infection over the years.

In addition to the impact on RV-specific hospitalization, our data suggest that introduction of RV5 resulted in a significant decrease in all-cause AGE-related activity seen by a primary pediatric practice: ~25% and 50% for office visits and hospitalizations, respectively. The decrease started in 2006–2007, when 11% of age-eligible children received ≥1 dose of RV5, and became more pronounced in 2007–2008 and 2008–2009, when the proportion of vaccinated children increased to 40% to 46%, suggesting that use of the vaccine was associated with the decrease in AGE activity. Also supportive of the possibility that RV5 was the cause of decreased AGE activity are that the decrease was more pronounced among hospitalized patients (a characteristic of RV disease); that in cases that were tested, the decrease was specific for RV-positive diarrhea (50%–85%); and that among the RV5-eligible children, there was a negative association between presenting with RV diarrhea and documentation of having received RV5. Because we had only 1 prevaccine year with good data to use as comparison, however, we cannot state conclusively that RV5 vaccination led to the decreased AGE activity. Theoretically, the time trends found in our study may be caused by year-to-year variability in AGE and RV activity. Additional years of surveillance will be needed to clarify this issue. Meanwhile, data that validate the postlicensure efficacy of RV5 to prevent RV hospitalization in the United State are emerging.[15,16] Similar to us, 1 of these studies detected a 28% (95% CI: 22%–33%) reduction in outpatient all-cause AGE.[15]

In 2007–2008 and 2008–2009 (combined), children who were younger than 2 years had a marked decrease (>81%) in RV-positive AGE seen (either ED only or hospitalized), despite that only 40% to 46% of age-eligible children received ≥1 dose of RV5. This suggests a herd-immunity effect by RV vaccination with substantial benefit to unvaccinated or undervaccinated children. This herd-immunity effect is further supported by the fact that children who were aged ≥2 years (who had not received the vaccine) also had a decrease in RV-related visits (41%); although the trend was strong, it did not reach significance, probably because of small numbers. Our database contained some groups of siblings, but they were too few to explain the herd-immunity effect. During 2007–2009, RV5-vaccinated children and their siblings accounted for only 27.6% of the surveillance population. It would seem that the herd-immunity effect was community-wide and not restricted to household exposure. Similar results were recently reported by the state of New York, where hospital discharge data comparing 2008 with 2003–2006 detected an 83% and 70% decrease in diarrhea admissions as a result of RV among children who were aged 1 to 23 months (vaccine eligible) and older unimmunized children, respectively (the level of use of RV vaccine in the community was unknown), with 40% reduction in all-cause diarrhea-associated hospitalization.[17] No national data on RV vaccine coverage is available and rates are likely to differ by location. Our vaccination rates are within the range of those reported by others for the 2006–2007 (21%–65%) and 2007–2008 (12%–76%) RV season periods.[7,18]

Some limitations of our study must be considered. First, ~22% of children were lost to the practice every year; the reasons are unclear as are their risk for AGE or likelihood of receiving the vaccine. Second, denominator (children who were younger than 5 years in the practice) and numerator (cases of AGE) numbers were identified by entry in the database, so it would favor those who are more likely to be seen either for well or sick visits. Third, AGE was defined by *International Classification of Diseases, Ninth Revision* codes, and inappropriate coding

has been documented by others.[2,9] Fourth, a chart audit suggested that the database would underestimate the vaccination status of the patients in 9% of the cases (6.5% because of doses given outside CHMPC and 2.5% because of data not recorded). Fifth, RV testing was not systematic but at the discretion of the hospital physician. Still, it was performed in 89% of CHMPC's AGE cases during RV season and 73% during non-RV season, so only a few cases would have been missed. Sixth, patients who were admitted to a hospital other than CHNO may not have been detected by our system. This seems unlikely, though, because CHMPC providers consistently advise patients to use CHNO for ED visits or hospitalizations and we did not detect an instance in our review of 200 records. Seventh, our findings correspond to 1 large practice, and it is not clear how well this practice represents the experience of other practices in the region or nationally. Finally, this was a short-term evaluation of RV5. The trend may change in the future: on the 1 hand, additional decrease in RV activity may be seen as the vaccine is more widely used, but on the other hand, RV activity may recrudesce if unusual serotypes that are not covered by the vaccine emerge. Once again, additional surveillance years will be needed to clarify this issue.

## CONCLUSIONS

Coincidental with increased use of RV5 in a primary practice (up to 40%–46%), we found a decrease not only in RV hospitalizations (50%), as previously described, but also in the total number of AGE office visits (23%). The decrease in RV disease was detected not only among young children who were targeted for immunization (81%) but also among older children (41%), suggesting a significant herd-immunity effect.

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