Variation in Rotavirus Vaccine Coverage by Provider Location and Subsequent Disease Burden

Leila C. Sahni, MPH², Jacqueline E. Tate, PhD¹, Daniel C. Payne, PhD, MSPH², Umesh D. Parashar, MBBS, MPH², Julie A. Boom, MDᵃ,c

abstract

BACKGROUND: Rotavirus vaccines were introduced in the United States in 2006. Full-series coverage is lower than for other vaccines, and disease continues to occur. We examined variation in vaccine coverage among provider locations and correlated coverage with the detection of rotavirus in children who sought treatment of severe acute gastroenteritis (AGE).

METHODS: Vaccine records of children enrolled in an AGE surveillance program were obtained and children were grouped by the location that administered each child’s 2-month vaccines. Cases were children with laboratory-confirmed rotavirus AGE; controls were children with rotavirus-negative AGE or acute respiratory infection. Location-level coverage was calculated using ≥1 dose rotavirus vaccine coverage among controls and classified as low (<40%), medium (≥40% to <80%), or high (≥80%). Rotavirus detection rates among patients with AGE were calculated by vaccine coverage category.

RESULTS: Of controls, 80.4% (n = 1123 of 1396) received ≥1 dose of rotavirus vaccine from 68 locations. Four (5.9%) locations, including a NICU, were low coverage, 22 (32.3%) were medium coverage, and 42 (61.8%) were high coverage. In low-coverage locations, 31.4% of patients with AGE were rotavirus-positive compared with 13.1% and 9.6% in medium- and high-coverage locations, respectively. Patients with AGE from low-coverage locations had 3.3 (95% confidence interval 2.4–4.4) times the detection rate of rotavirus than patients with AGE from high vaccine coverage locations.

CONCLUSIONS: We observed the highest detection of rotavirus disease among locations with low rotavirus vaccine coverage, suggesting that ongoing disease transmission is related to failure to vaccinate. Educational efforts focusing on timely rotavirus vaccine administration to age-eligible infants are needed.

WHAT’S KNOWN ON THIS SUBJECT: Uptake of rotavirus vaccines has increased steadily since introduction. Despite their demonstrated impact, rotavirus vaccine coverage is lower than for other vaccines recommended in infancy and disease continues to occur.

WHAT THIS STUDY ADDS: We observed higher rotavirus detection rates among patients from provider locations with lower rotavirus vaccine coverage; providers who do not offer rotavirus vaccine to age-eligible children may create pockets of susceptible children that serve as reservoirs of ongoing disease transmission.

¹Immunization Project, Texas Children’s Hospital, Houston, Texas; ²Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; and ³Department of Pediatrics, Baylor College of Medicine, Houston, Texas

Ms Sahni conceptualized and designed the study, coordinated and supervised data collection, and drafted the initial manuscript; Dr Tate conceptualized and designed the study, carried out the initial analyses, and reviewed and revised the manuscript; Drs Payne and Parashar conceptualized and designed the study, and reviewed and revised the manuscript; Dr Boom conceptualized and designed the study, and drafted the initial manuscript; and all authors approved the final manuscript as submitted.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.


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Before the introduction of rotavirus vaccines in the United States, approximately 30% to 50% of hospitalizations for severe acute gastroenteritis (AGE) in US children were attributed to rotavirus.1–3 Two live attenuated, oral vaccines are currently licensed and recommended for use in the United States: a 3-dose pentavalent vaccine (RotaqTeq [RV5]; Merck Vaccines, Whitehouse Station, NJ), licensed in 2006, and a 2-dose monovalent vaccine (Rotarix [RV1]; GlaxoSmithKline Biologicals, Rixensart, Belgium), licensed in 2008. The US Advisory Committee on Immunization Practices (ACIP) recommends that doses of either vaccine be administered at 2 and 4 months of age, with the third dose of RV5 administered at 6 months of age. Specifically, ACIP states that the first dose of either rotavirus vaccine may be administered as early as 6 weeks of age and no later than 14 weeks 6 days, whereas the final dose of vaccine must be administered by 8 months 0 days of age.4

Uptake of rotavirus vaccines has steadily increased each year since introduction, with national full-series coverage (either 2 or 3 doses depending on vaccine type) reaching 67% in 2011.5 Concomitantly, the burden of rotavirus AGE has declined dramatically in the years after vaccination, with studies estimating a 60% to 89% reduction in hospitalizations due to rotavirus among children <5 years of age.2,6,7 Despite the demonstrated impact of rotavirus vaccines, full-series coverage 5 years after introduction of rotavirus vaccine remains lower than for other vaccines recommended at 2, 4, and 6 months of age, for which coverage is 93% to 95%.5 There are several reasons this discrepancy may exist: the narrow age ranges during which the first and final doses of rotavirus vaccine may be administered,4 lingering safety concerns after withdrawal of the RotaShield vaccine in 1999,8–10 hesitancy about use of a new live attenuated oral vaccine, and issues regarding vaccine cost and insurance reimbursement.9,10

Texas Children’s Hospital (TCH) conducts active surveillance for severe AGE as part of the New Vaccine Surveillance Network.11 During routine surveillance, we anecdotally noticed that a high proportion of rotavirus-positive cases were occurring among patients from a small number of individual provider locations. As vaccine purchasing and administration policies are typically determined at the provider level, we hypothesized that the high proportion of rotavirus-positive cases observed at some provider locations could be associated with lower rotavirus vaccine coverage at these sites. To explore this further, we examined the vaccine records of children enrolled in our routine AGE and acute respiratory infection (ARI) surveillance initiative to evaluate variation in rotavirus disease by vaccine coverage at each location and correlated coverage with the detection of rotavirus in children who sought treatment of severe AGE.

METHODS

At the emergency department of TCH in Houston, we conducted active surveillance for children <5 years of age who sought treatment of AGE (≥3 loose stools and/or ≥1 episode of vomiting) during the months of highest rotavirus activity, November 2009 through June 2010 (“2009–2010 rotavirus season”) and November 2010 through June 2011 (“2010–2011 rotavirus season”). Patients with AGE were consented for enrollment and fecal specimens were collected within 14 days of illness onset (82% of specimens were collected within 7 days of illness onset) to test for rotavirus by using a commercial enzyme immunoassay (Premier Rotaclone; Meridian Biosciences, Inc, Cincinnati, OH). We conducted a case-control assessment of rotavirus vaccine effectiveness in conjunction with surveillance activities. Cases were children with laboratory-confirmed rotavirus gastroenteritis who were identified through AGE surveillance. Two distinct control groups were used: children identified through AGE surveillance who had rotavirus-negative AGE and children with ARI who were identified and enrolled during the AGE surveillance period to serve as controls for the vaccine-effectiveness assessment. Contact information for up to 3 immunization providers was obtained from the parent/guardian during enrollment for all children, and permission was obtained to contact these providers for vaccine information. Permission was also obtained to search the Texas statewide immunization information system, ImmTrac. Results of the case-control evaluation are presented elsewhere.12

This assessment used the cases and controls from the vaccine-effectiveness assessment. Rotavirus vaccine information, including date of administration, dose number, vaccine type, and name of the administering provider location was abstracted from vaccine records for cases and controls. Provider location was defined as ≥1 medical providers treating children at the same physical location. Children were grouped by the location that administered each child’s 2-month vaccines, and characteristics (public, private, hospital affiliation, multiple locations) describing each location were obtained. The 2-month visit was selected because it is unlikely that children receiving vaccines at subsequent visits would be age-eligible to receive rotavirus vaccine if the first dose had not previously been administered at the 2-month visit; therefore, the burden of rotavirus vaccine series initiation lies with the provider of 2-month vaccines. If needed, parents were recontacted by phone to confirm the provider location that administered 2-month vaccines.
Children for whom a vaccine record could not be obtained, whose provider of 2-month vaccines could not be identified, who were vaccinated outside the Greater Houston area, who were >2 months of age but had received no 2-month vaccines, who were too young to have received rotavirus vaccine (<42 days of age), or who were born before rotavirus vaccine licensure (born before April 1, 2006) were excluded from analyses (Fig 1). Analyses were restricted to provider locations from which ≥10 controls were enrolled during the 2-year study period to avoid artificial skewing of coverage based on a small number of subjects; cases were excluded from analyses if they received their 2-month vaccines from a location with <10 controls enrolled. For children with multiple hospital visits during the 2 combined surveillance seasons, only the first visit was included.

For each provider location from which ≥10 controls were enrolled, vaccine coverage with ≥1 dose of any rotavirus vaccine was calculated by dividing the number of controls who received at least 1 dose of rotavirus vaccine by the total number of controls enrolled from that location. We examined the distribution of vaccine coverage levels by individual provider location and created a 3-level categorical vaccine coverage

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**FIGURE 1**
Flow diagram of participant inclusion in analysis for rotavirus-positive cases, and rotavirus-negative AGE and ARI controls. RV+, rotavirus-positive; RV−, rotavirus-negative.
variable. Provider locations with ≥1 dose coverage of <40% were considered low coverage, provider locations with coverage of ≥40% to <80% were considered medium coverage, and those with coverage ≥80% were considered high coverage provider locations. The cutpoints for the coverage groups were selected a priori. However, in sensitivity analyses, numerous cutpoints for inclusion of the practices in the low-coverage group were examined.

Categorical variables were compared by using \( \chi^2 \) analyses and medians were compared by using the Wilcoxon rank-sum test. A generalized linear model with Poisson family, log link, and robust error variance was used to compare the rotavirus detection rates in the different coverage groups. All analyses were performed by using SAS 9.3 (SAS Institute, Inc, Cary, NC).

This study was reviewed and approved by institutional review boards at Baylor College of Medicine and Texas Department of State Health Services. Informed consent was obtained from participants’ parents/guardians.

**RESULTS**

A total of 2197 children with AGE and 1523 children with ARI were enrolled during the 2009–2010 and 2010–2011 rotavirus seasons. After excluding ineligible children and restricting analyses to provider locations from which ≥10 controls were enrolled, a total of 100 rotavirus-positive cases, 725 rotavirus-negative AGE controls, and 670 ARI controls were included in this assessment (Fig 1). Of the 1395 included control children (725 rotavirus-negative AGE and 670 ARI controls), 80.4% (n = 1122) had received ≥1 dose of rotavirus vaccine and were vaccinated by 68 different locations. Four (5.9%) locations, including a NICU, were classified as low coverage (≥1 dose coverage of <40%), 22 (32.3%) locations were classified as medium coverage (≥1 dose coverage of ≥40% to <80%), and 42 (61.8%) were classified as high coverage (≥1 dose coverage of ≥80%) (Table 1).

All provider locations in each of the coverage categories were pediatric only (no family physicians) and most were affiliated with academic institutions (Table 1). Within each coverage category, the proportion of AGE cases that were due to rotavirus varied (Fig 2).

The proportion of children age-eligible to have received a complete series (≥8 months of age) was similar across coverage categories (74% in low- and medium-coverage locations and 70% in high-coverage locations). The distribution of rotavirus vaccine doses among children age-eligible for a full series varied by provider location coverage category. In low-coverage locations, 12.5% (6 of 48) of these age-eligible children were fully vaccinated (2 doses of RV1 or 3 doses of RV5) compared with 49.3% (184 of 373) of children at medium-coverage locations and 67.9% (395 of 582) of children at high-coverage locations. Conversely, 87.5% (42 of 48) of children age-eligible to have received a full series in low-coverage locations had received no doses of rotavirus vaccine, compared with 29.5% (110 of 373) of children in medium-coverage locations and 10.3% (60 of 582) of children in high-coverage locations (Table 2).

We observed differences in the age of vaccinated and unvaccinated controls across all coverage categories. Children who had received ≥1 dose of rotavirus vaccine were younger than children who had received no doses of vaccine (12.9 vs 22.5 months [P < .001], respectively). The age of vaccinated children in low-coverage provider locations was similar to the ages of those belonging to medium- and high-coverage locations (Table 2).

In low-coverage locations, rotavirus was detected in 31.4% of patients with AGE compared with 13.1% and 9.6% in medium- and high-coverage locations, respectively. From the Poisson model, patients with AGE from low-coverage locations had 3.3

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**TABLE 1** Summary of AGE Case and Control Enrollment and Type of Provider Locations by Coverage Level Category

<table>
<thead>
<tr>
<th>Rotavirus Vaccine Coverage Levels in Controls</th>
<th>&lt;40%</th>
<th>≥40% to &lt;80%</th>
<th>≥80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of provider locations</td>
<td>4</td>
<td>22</td>
<td>42</td>
</tr>
<tr>
<td>Median no. of AGE cases per provider location (range)</td>
<td>14.5 (6–16)</td>
<td>9.5 (3–33)</td>
<td>9.5 (4–43)</td>
</tr>
<tr>
<td>Median % of rotavirus-positive cases per provider location (range)</td>
<td>33.3 (25.0–35.7)</td>
<td>12.4 (0.0–29.6)</td>
<td>9.2 (0.0–26.7)</td>
</tr>
<tr>
<td>Median no. of controls per provider location (range)</td>
<td>17.5 (11–19)</td>
<td>19 (10–65)</td>
<td>16 (10–62)</td>
</tr>
<tr>
<td>Median % of controls with ≥1 dose of rotavirus vaccine per provider location (range)</td>
<td>8.5 (0.0–36.4)</td>
<td>74.7 (40.0–78.8)</td>
<td>90.5 (80.0–100.0)</td>
</tr>
<tr>
<td>Type of provider location</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Public providers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital affiliated</td>
<td>2 (8.1)</td>
<td>2 (8.1)</td>
<td>2 (8.1)</td>
</tr>
<tr>
<td>Local health department</td>
<td>3 (13.7)</td>
<td>2 (8.1)</td>
<td>2 (8.1)</td>
</tr>
<tr>
<td>Federally qualified health center</td>
<td>1 (4.5)</td>
<td>1 (4.5)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Private providers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital affiliated</td>
<td>7 (31.8)</td>
<td>15 (55.7)</td>
<td>15 (55.7)</td>
</tr>
<tr>
<td>Single location</td>
<td>3 (75.0)</td>
<td>8 (35.4)</td>
<td>22 (52.4)</td>
</tr>
<tr>
<td>Multiple locations</td>
<td>1 (4.5)</td>
<td>2 (8.1)</td>
<td>2 (8.1)</td>
</tr>
<tr>
<td>NICU</td>
<td>1 (25.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

— no provider locations of this type in this coverage level.
times the detection rate of rotavirus than that of patients with AGE in the high vaccine coverage locations. There was no significant difference in rotavirus-detection rates between children with AGE in the medium- and high-coverage provider locations (Incidence Rate Ratio 1.4 [95% confidence interval 0.9–2.1]). Results were consistent across rotavirus seasons when each season was analyzed separately. In sensitivity analyses, we repeated the analyses with numerous different cutpoints for the low-coverage category but no impact was observed on the results.

**DISCUSSION**

We examined rotavirus vaccination coverage at high-volume pediatric provider locations whose patients used the TCH emergency department during the 2-year study period. Of the 68 locations identified, 42 (62%) had high rotavirus vaccine coverage levels, whereas 22 (32%) had medium rotavirus vaccine coverage levels, and 4 (6%) had low rotavirus vaccine coverage rates. Three of the 4 low-coverage locations are private pediatric primary care offices, whereas the fourth location represents children hospitalized in a NICU at the time of 2-month vaccinations. Although only 4 (6%) of the 68 provider locations included in this analysis were designated as low coverage (<40%), 16% (n = 16 of 100) of all rotavirus-positive children enrolled during the 2-year study period received their 2-month vaccinations at 1 of these locations. Furthermore, a tendency toward increasing detection of rotavirus in patients with AGE with decreasing provider-level rotavirus vaccine coverage was observed, with children from low-coverage locations having more than 3 times higher detection rates of rotavirus than in children from high-coverage locations. Collectively, these findings indicate that failure to vaccinate is contributing, at least in part, to the lower but persistent burden of rotavirus AGE in the post-rotavirus vaccine era.

As a detailed characterization of the provider locations and the vaccine attitudes of parents treated at these locations was not an objective of this study, the reason for the low rotavirus vaccine coverage among some sites is unclear. However, the reasons for low rotavirus vaccine coverage among
NICU children are identifiable and complex. Because rotavirus vaccine is a live, attenuated orally administered vaccine and shedding of vaccine virus is known to occur after administration,\textsuperscript{13–16} ACIP recommends vaccination of age-eligible infants at the time of NICU discharge and not during hospitalization.\textsuperscript{4} An assessment of rotavirus vaccination status among very low birth weight infants at NICU discharge found that >50% of infants included in the assessment were age-eligible to have received rotavirus vaccine at discharge.\textsuperscript{17} Although this assessment was conducted in a single NICU, it is reasonable to expect that many infants hospitalized in other NICUs also would be age-eligible to initiate rotavirus vaccine at discharge. Infants discharged from a NICU are frequently underimmunized for all 2-month vaccinations\textsuperscript{18}, specific to rotavirus vaccine, we believe that this underimmunization may be exacerbated by the logistical challenges of vaccine administration at the time of NICU discharge and not during hospitalization. If rotavirus vaccine is not given during NICU hospitalization or at discharge, pediatricians in the community may fail to realize this, may presume that the vaccine had been omitted for a specific reason, or may have doubts about administering vaccine to a fragile, medically complex infant. Unfortunately, failure to vaccinate these vulnerable infants may result in severe disease requiring medical attention.\textsuperscript{19,20} Given the current, explicitly defined ACIP recommendation, infants hospitalized in a NICU for ≥15 weeks may lose the window of eligibility to receive rotavirus vaccine.

Unvaccinated children in this study were older than children who had received ≥1 dose of vaccine. This is not surprising, given the increasing level of rotavirus vaccine coverage over the years. This difference in age between vaccinated and unvaccinated children is smallest among children at high-coverage locations, which suggests that these providers may have adopted rotavirus vaccine recommendations earlier than providers at low- and medium-coverage locations. Similarly, high-coverage locations had the smallest proportion of unvaccinated children among those age-eligible to have received a full series of rotavirus vaccine compared with the medium- and low-coverage sites.

This study has several limitations. First, children were assigned to the provider location where their 2-month vaccines were administered by using information obtained from their vaccine record. If the child’s 2-month vaccines were documented as historical data but not indicated as such either on the record or to our study staff, a miscategorization may have occurred. We believe that any such miscategorization would have been equally likely to occur among all locations, regardless of the coverage category to which they were assigned. Second, because provider locations were required to have ≥10 controls enrolled during the 2-year study period, smaller locations and sites that infrequently had children visit TCH were excluded from analysis. This resulted in the elimination of 91 rotavirus-positive cases and 979 combined rotavirus-negative AGE and ARI controls; however, children from included and excluded practices were of similar ages and had similar rotavirus vaccine coverage. Our small sample size precluded some statistical analyses; however, this assessment was exploratory in nature and suggests the need for larger future studies to confirm our findings. Third, we did not control for provider location size. Given the large number of locations included in this study, it was not feasible to obtain information about the size of each location’s active patient population. This assessment was conceived after patient enrollment had concluded, and information about each location’s patient population size during the study period was not obtained. Attempting to obtain retrospective estimates of each location’s active patient population would likely be inaccurate. For these reasons, attack rates were calculated using the total number of children treated for AGE at TCH. If either the proportion of children with medically attended AGE at TCH varied or the

### TABLE 2 Characteristics of AGE Cases and Controls by Provider Location Coverage Level Category

<table>
<thead>
<tr>
<th>Rotavirus Vaccine Coverage Levels in Controls</th>
<th>&lt;40%</th>
<th>≥40% to &lt;80%</th>
<th>≥80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of AGE cases</td>
<td>51</td>
<td>274</td>
<td>500</td>
</tr>
<tr>
<td>No. of rotavirus-positive cases</td>
<td>16</td>
<td>36</td>
<td>48</td>
</tr>
<tr>
<td>% of rotavirus-positive cases</td>
<td>31.4</td>
<td>13.1</td>
<td>9.6</td>
</tr>
<tr>
<td>Total no. of controls</td>
<td>65</td>
<td>501</td>
<td>829</td>
</tr>
<tr>
<td>No. of controls with ≥1 dose of rotavirus vaccine</td>
<td>7</td>
<td>563</td>
<td>752</td>
</tr>
<tr>
<td>% of controls with ≥1 dose of rotavirus vaccine</td>
<td>10.8</td>
<td>72.5</td>
<td>90.7</td>
</tr>
<tr>
<td>No. (% of) doses of rotavirus vaccine received among children ≥8 mo of age\textsuperscript{a}</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>42 (87.5)</td>
<td>110 (28.5)</td>
<td>60 (10.3)</td>
</tr>
<tr>
<td>1</td>
<td>0 (0.0)</td>
<td>31 (8.1)</td>
<td>41 (7.0)</td>
</tr>
<tr>
<td>2</td>
<td>1 (2.1)</td>
<td>48 (13.1)</td>
<td>86 (14.8)</td>
</tr>
<tr>
<td>3</td>
<td>5 (10.4)</td>
<td>183 (49.1)</td>
<td>395 (67.9)</td>
</tr>
<tr>
<td>Total</td>
<td>48 (100.0)</td>
<td>373 (100.0)</td>
<td>582 (100.0)</td>
</tr>
</tbody>
</table>

\textsuperscript{a} All except 4 children received RV5. Of the 4 children who received RV1, 2 received 1 dose and 2 received 2 doses. One of the 2-dose RV1 recipients was from a low-coverage location (<40%) and the other from a medium-coverage location (≥40% to <80%). Thus, 6 (12.5%) of 48 children in low-coverage locations, 184 (49.3%) of 373 children in medium-coverage locations, and 395 (67.9%) of 582 children in high-coverage locations were fully vaccinated.
The proportion of children who acquired AGE varied by location, this may have influenced our results. Similarly, we estimated provider-level coverage rates from rotavirus-negative patients with AGE and ARI controls who sought treatment at TCH. If these vaccinated and unvaccinated children differentially sought care at TCH or were not representative of the larger patient population, then our results may be biased. Fourth, because we did not evaluate parental vaccine beliefs and attitudes, it was not possible to determine whether children did not receive rotavirus vaccine because of parent request or because of provider vaccination practices. Excluding children who had received no vaccines other than a birth-dose of hepatitis B vaccine could have biased our findings in either direction. If these children had actually received rotavirus vaccine at 2 months of age, this would have resulted in an underestimation of rotavirus vaccine coverage. Conversely, nonreceipt of rotavirus vaccine because of parental refusal would have overestimated rotavirus vaccine coverage. Given the small number of children in this assessment for whom documentation of only hepatitis B vaccine was obtained \((n = 17)\) and the relatively low rate of vaccine exemptions in Texas,\(^1\) it is unlikely that this had a major impact on our findings. Fifth, most included provider locations were affiliated with academic institutions and may not be representative of all provider sites in the greater Houston area. Similarly, because this study was conducted at a single site, it may not be representative of rotavirus vaccine coverage and disease rates in the United States.

**CONCLUSIONS**

In this study, we observed higher detection rates of rotavirus among patients with AGE from provider locations with lower rotavirus vaccine coverage, including in hospitalized infants who were scheduled to receive their 2-month vaccines in a NICU. These findings suggest that the failure of providers to consistently offer rotavirus vaccine to age-eligible children may result in susceptible children who serve as reservoirs of ongoing disease transmission. Initiating rotavirus vaccination at the time of NICU discharge has logistical challenges and infants may no longer be age-eligible, thereby leaving these vulnerable infants unvaccinated. Studies to assess the potential risks of nosocomial transmission of rotavirus vaccine strains in the NICU will help weigh the risks and benefits of vaccinating infants in the NICU. Educational efforts targeting vaccine providers, including NICU physicians and nurses, should focus on the importance of administration of rotavirus vaccine to every age-eligible child. Furthermore, local and state health departments should use their immunization information systems to identify provider locations where additional education about the importance of rotavirus administration may be needed.

**ACKNOWLEDGMENTS**

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