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Potential Impact of Accelerating the Primary Dose of Rotavirus Vaccine in Infants

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Abstract

We estimated the potential impact of administering the first dose of rotavirus vaccine at 6 weeks (42 days of life) instead of 2 months of age, which is permissible for all U.S. vaccines recommended at 2 months of age, on rotavirus hospitalization rates. We used published data for hospitalization rates, vaccine coverage, and vaccine efficacy after one dose and assumed a two-week delay in seroconversion after vaccine administration in the United States. Administering the first dose of rotavirus vaccine at 6 weeks instead of 8 weeks of age should have prevented 1110, 1660, and 2210 rotavirus hospitalizations among U.S. infants <3 months of age in 2006 when the vaccine was first introduced. This estimated benefit represents a 2%-4% reduction in rotavirus hospitalizations among children <5 years of age.

Keywords

rotavirus vaccine; infants; rotavirus; hospitalizations; prevention; epidemiology

Rotavirus accounted for approximately one-third to one-half of the estimated 150,000 to 200,000 hospitalizations for gastroenteritis in children younger than 5 years old in the United States annually prior to rotavirus vaccine introduction in 2006.¹⁻⁴ For each rotavirus hospitalization, the estimated median direct cost is \$4565, the average length of stay is 1.9 days, and parents lose 3.4 days of work.⁵ The global impact of rotavirus is even greater than that in the United States, with approximately 1400 to 1500 pediatric deaths daily or half a million pediatric deaths annually.^{6,7}

Two vaccines have been licensed to help prevent rotavirus infections in the United States: the pentavalent human-bovine vaccine (RotaTeq®, Merck) was licensed in February 2006 and the monovalent human attenuated vaccine (Rotarix®, GlaxoSmithKline) was licensed in April 2008. The Advisory Committee on Immunization Practices (ACIP) recommends

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administration of either vaccine beginning as early as six weeks of age (42 days of life), although they are typically administered at two months of age.⁸⁻¹⁰ We sought to estimate the potential effect of accelerating the primary dose of rotavirus vaccine from eight weeks to six weeks of age on rotavirus hospitalization rates.

Methods

We used published data to estimate rotavirus hospitalization rates in young infants in the United States. These estimates are based on rotavirus surveillance studies conducted before currently licensed rotavirus vaccines were introduced in 2006 and 2008. Investigators performed capture-recapture analysis to estimate the total rotavirus disease burden in Cincinnati, Ohio. These estimates were achieved by comparison of results of an active surveillance program for enteric infections with results from concurrent passive rotavirus surveillance based on physician-ordered testing. In 1997-2002 and 2005-2006 when both active and passive surveillance were on-going, the estimated hospitalization rate per 10,000 infants <3 months of age with laboratory-confirmed rotavirus infection was 52 (95% confidence interval 39-75).¹¹ This result was consistent with a study of children hospitalized with gastroenteritis from January 1974 through July 1982, which found similar numbers of rotavirus-positive stool specimens among infants 0-3 and 4-6 months of age.¹² Similarly, a retrospective stool analysis from children with diarrheal hospitalizations from 1994-2006 found that the peak age of laboratory-confirmed rotavirus hospitalizations was at 2 months of age.¹³ For this study, we assumed a baseline rotavirus hospitalization rate of 52 per 10,000 infants <3 months old.

We conservatively assumed a two-week delay in the direct immune response of an accelerated first dose of rotavirus vaccine, meaning that the benefit of vaccination at 6 weeks of age would be first seen at 8 weeks of age.

Vaccine efficacy has been documented for both the monovalent and pentavalent rotavirus vaccines. Partial series efficacy of monovalent rotavirus vaccine was 90% (95% CI 9-100%) after one dose against rotavirus gastroenteritis of any severity. Partial series efficacy of pentavalent rotavirus vaccine was 82% (95% CI 39-97%) against severe rotavirus disease starting at 14 days post-vaccination with the first dose.¹⁴ For this analysis we conducted a sensitivity analysis using conservative estimates of 40%, 60%, and 80% vaccine efficacy for a single dose of rotavirus vaccine.

For this analysis we assumed that 75% and 50% of infants were vaccinated, which is consistent with the 2010 national average vaccination coverage of 59% and the range by state of 42% to 82%.¹⁵

To determine the projected hospitalization rate after vaccination, we used the following formula: $[(\text{Hospitalization rate per 10,000}) \times (\text{Proportion not vaccinated})] + [(\text{Hospitalization rate}) \times (\text{Proportion vaccinated}) \times (1 - \text{Vaccine efficacy as a proportion})] = \text{Projected hospitalization rate per 10,000 after vaccination}$

The estimated number of hospitalizations prevented equaled the difference in pre-vaccine and projected hospitalization rates multiplied by the estimated 4,251,095 live births according to the 2008 U.S. Census and by 2/12 to account for the fact that vaccinating at 6 weeks instead of 8 weeks of life would impact 2 of the first 12 weeks of life.¹⁶ We calculated the number of infants that needed to be vaccinated at 6 weeks (42 days of life) instead of 8 weeks of age to prevent one rotavirus hospitalization (the “number needed to treat”, or NNT). This number was calculated by dividing the product of the total population of U.S. live births per the 2008 U.S. Census and the estimated proportion of infants that would be vaccinated by the estimated number of hospitalizations prevented; this NNT is

equivalent to Kelly et al's calculation of the number needed to be vaccinated as $1/(\text{annual disease rate among the unvaccinated} \times \text{vaccine effectiveness for that outcome})$.¹⁷

The approximate 95% confidence intervals (CI) were computed by applying these formulas to the published confidence bounds for the baseline hospitalization rate (39 and 75 per 10,000 infants), which assumes the number of live births, vaccination coverage and vaccine efficacy are known constants.

Statistical analyses were performed using S+ 8.1 (TIBCO Software Inc., Palo Alto, CA).

Results

We first estimated reductions in rotavirus hospitalization rates assuming that 75% of infants received the first dose of rotavirus vaccine at 6 weeks of age instead of 8 weeks, and a baseline rate of 52 rotavirus hospitalizations per 10,000 infants <3 months of age before introduction of currently licensed rotavirus vaccines in the United States (**Table**). If the single-dose vaccine efficacy is estimated to be 40%, rotavirus hospitalization rates for infants with 2 additional weeks of protection in the first 12 weeks of life would be expected to drop by 5%. In that case first-dose acceleration of rotavirus vaccine from 8 weeks to 6 weeks of age has the potential to prevent 1110 hospitalizations. If the single-dose vaccine efficacy is estimated to be 60%, rotavirus hospitalization rates for infants would be expected to drop by 7.5%, with first-dose acceleration preventing 1660 hospitalizations. If the single-dose vaccine efficacy is estimated to be 80%, rotavirus hospitalization rates for infants would be expected to drop by 10%, with first-dose acceleration preventing 2210 hospitalizations.

We next used these same assumptions to perform number needed to treat (NNT) analyses. If the single dose vaccine efficacy is estimated to be 40%, the number of infants that needed to be vaccinated at 6 weeks instead of 8 weeks of age to prevent one rotavirus hospitalization, or NNT, was 2880 (**Table**). For vaccine efficacy of 60% and 80%, the NNT was 1920 and 1440, respectively.

The benefit of first-dose acceleration would be less if a smaller percentage of the population received the rotavirus vaccine. The estimated reductions in rotavirus hospitalization rates assuming that 50% of infants received the first dose of rotavirus vaccine at 6 weeks of age instead of 8 weeks would be lower. Because the estimated number of vaccinated infants would decrease proportionally in this scenario, the NNT remains the same.

Discussion

Vaccination is an important public health achievement that has resulted in a 99.7% reduction in childhood mortality from major infectious diseases between 1900 and 1998.¹⁸ Efforts to improve vaccine efficacy and uptake are important areas of focus as we improve childhood health. Rotavirus is a significant source of morbidity and mortality for young children worldwide. Two rotavirus vaccines were recently licensed for use in the United States and have significantly decreased disease incidence in this country.^{19,20} In this study, we evaluated the potential impact of accelerating administration of the first dose of rotavirus vaccine from 8 weeks to 6 weeks of age. We estimated that this change could have prevented 1110 to 2210 rotavirus hospitalizations among infants <3 months of life if 75% of infants were vaccinated at 6 weeks of age when rotavirus vaccine was first introduced. With the estimated direct cost of \$4565 per rotavirus hospitalization,⁵ preventing 1110 to 2210 rotavirus hospitalizations among U.S. infants in 2006 when rotavirus vaccine was introduced could have yielded a cost savings of approximately \$5 to \$10 million dollars. Vaccinating 75% of U.S. infants 2 weeks earlier when the vaccine was initially licensed could have

prevented an estimated 2-4% of the estimated 60,000 rotavirus hospitalizations among children <5 years of age.⁴ To our knowledge, this is the first study to estimate the potential impact on rates of rotavirus hospitalization from first-dose acceleration of rotavirus vaccine.

Curns and colleagues have recently published estimates of the future impact of rotavirus vaccine use in the United States on rotavirus hospitalization rates. Using national hospitalization data for acute gastroenteritis, they estimated that the decrease in overall acute gastroenteritis hospitalizations from rotavirus should be detectable in 2009 for children <1 year age, in 2010 for children 1 year of age, and in 2011 for children <5 years of age.²¹ Our study suggests that first-dose acceleration of rotavirus vaccine would have resulted in additional decreases in rotavirus hospitalizations if implemented when the vaccine was initially licensed.

Several studies have examined the effects of accelerating the first dose of other childhood vaccines. Early administration of the diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) at 6 weeks of age could prevent 1236 cases of pertussis, 898 hospitalizations, and 7 deaths attributable to pertussis per year in the United States.²² In Australia, accelerated administration of DTaP was estimated to prevent 9% of hospitalizations and 12% of hospital bed-days attributable to pertussis in infants.²³ Study of a pertussis outbreak in Arizona resulted in the finding that the proportion of infants who completed the primary series of DTaP (along with the other routine vaccines) within the first 6 months of life was higher for those who received vaccines at the minimal dosing interval than at the standard interval.²⁴ Similarly, early administration of the pneumococcal conjugate vaccine could prevent approximately 100 cases of invasive pneumococcal disease among young infants in the United States.²⁵

Of note, all of the vaccines routinely given at 2 months of age can also be given at 6 weeks of age in keeping with current ACIP guidelines. Early administration of all of the scheduled primary vaccines could in fact be accomplished without extra office visits by scheduling a routine well-child check at 6 weeks instead of 2 months.²² However, it is important to emphasize that vaccination at 6 weeks of life (42 days of life) is acceptable but vaccination before 38 days of life is not and would result in the need for revaccination.

One concern with accelerated vaccine administration relates to the potential consequences of fever occurring in 6 week old infants as a result of rotavirus vaccination. This could lead to increased diagnostic testing or hospitalizations. While this is certainly possible, it has not been reported in the published placebo-controlled, randomized controlled trials of rotavirus vaccine performed in infants in Asia, in South Africa and Malawi, and in sub-Saharan Africa which permitted vaccination as early as 6 weeks of age. The vaccine and placebo groups for all these trials reported similar proportions with adverse events.²⁶⁻²⁸ Another theoretical concern with this approach is that parental perspectives on vaccination may differ for children at 6 weeks and 2 months of age.

This study has several limitations. Our analysis uses baseline rates of rotavirus hospitalizations in infants that were measured before 2006, and including the 1-year period after August 1998. During that period another rotavirus vaccine (RotaShield®) was licensed in August 1998 and administered to infants for almost 1 year before being withdrawn.²⁹⁻³¹ The use of this prior rotavirus vaccine may have decreased estimates of rotavirus hospitalization rates used in our analysis to result in an underestimation of the potential impact of rotavirus vaccine first-dose acceleration. Our study estimates the decrease in rotavirus hospitalizations resulting from direct protection from the vaccine only. In the absence of empiric data about the vaccine efficacy of rotavirus vaccine at 6 weeks of age, we assumed the vaccine efficacy at 6 weeks of age would be the same as that reported at 8

weeks of age. We would have underestimated the potential impact if there is both direct and indirect protection resulting from ongoing rotavirus vaccine use and increased vaccine uptake in the population. The impact of early vaccination would be greatest when a new vaccine is licensed and would decrease as exposure of young infants to rotavirus decreases. Without published rates of rotavirus hospitalizations among children <3 months of age since licensure of the 2006 and 2008 rotavirus vaccines, we cannot estimate the extent to which this initial benefit would decrease. Yet, many nations around the world have not yet implemented rotavirus vaccination.³² Also, if the genotypes of rotavirus change sufficiently such that rotavirus hospitalizations increase and a new rotavirus vaccine is developed, then the same theoretic benefit could occur when this new vaccine is administered but with revised estimates on the baseline hospitalization rate and vaccine efficacy. Lastly, we computed the approximate 95% confidence intervals accounting for the published confidence bounds for the baseline hospitalization rate and assuming the number of live births, vaccination coverage and vaccine efficacy are known constants. Although each confidence interval does not account for variations in vaccine efficacy or vaccine coverage, the sensitivity analyses does provide estimates in the plausible ranges of both vaccine efficacy and vaccine coverage. Additionally, this statistical approach allows others to make straightforward estimates of benefit from earlier rotavirus vaccination, using data from other countries and clinical settings.

Furthermore, this study did not examine the potential effect of acceleration of the second and third doses of rotavirus vaccine that is also permitted by current ACIP guidelines.

This study estimates the potential benefits of accelerating the first dose of rotavirus vaccine at the time of vaccine introduction. Vaccine acceleration could be achieved without an increase in the number of office visits, and similar benefits have been demonstrated for several of the other vaccinations traditionally given at 2 months of age. Therefore, a simple modification in the schedule of pediatric office visits could result in a substantial reduction in disease burden among young infants.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
CI	confidence interval
NNT	Number Needed to Treat
U.S.	United States
VE	vaccine efficacy

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Highlights

- Rotavirus vaccine can be administered at 6 weeks instead of 2 months of age.
- Administering this vaccine 2 weeks earlier should reduce rotavirus hospitalizations.
- The estimated benefit is 2-4% fewer pediatric rotavirus hospitalizations.

Table

Projected Effect of Accelerating the First Dose of Rotavirus Vaccine from 8 Weeks to 6 Weeks of Age on Baseline of 52 Hospital Admissions Due to Rotavirus Gastroenteritis per 10,000 Infants assuming 75% or 50% of infants are vaccinated.

Prevaccine incidence per 10,000 infants	Vaccine Efficacy	Projected incidence per 10,000 infants	Estimated # of Hospitalizations Prevented N (95% CI)	Number Needed to Treat [*] N (95% CI)
Assumes 75% of infants are vaccinated				
52	40%	36.4 (27.3-52.5)	1110 (829-1590)	2880 (2000-3850)
	60%	28.6 (21.5-41.3)	1660 (1240-2390)	1920 (1330-2560)
	80%	20.8 (15.6-30.0)	2210 (1660-3190)	1440 (1000-1920)
Assumes 50% of infants are vaccinated				
52	40%	41.6 (31.2-60.0)	737 (553-1060)	2880 (2000-3850)
	60%	36.4 (27.3-52.5)	1110 (829-1590)	1920 (1330-2560)
	80%	31.2 (23.4-45.0)	1470 (1110-2130)	1440 (1000-1920)

* Number Needed to Treat is the estimated number of infants who need to be vaccinated at 6 weeks of age instead of 8 weeks of age to prevent one rotavirus hospitalization.