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Impact of Rotavirus Vaccination on Rotavirus Hospitalizations in Taiwanese Children

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Introduction

Rotavirus is a leading cause of severe acute gastroenteritis (AGE) among children worldwide, estimated to cause >125,000 deaths annually [1, 2]. In Taiwan, rotavirus vaccines are not part of the national immunization schedule, but two have been licensed and available for out-of-pocket purchase since 2006: Rotarix® (GlaxoSmithKline) and RotaTeq® (Merck), both live, oral, attenuated vaccines given to young infants (series recommended to be completed by 8 months of age). Prior to the introduction of rotavirus vaccines in Taiwan, rotavirus accounted for an estimated 20 – 43% of pediatric hospitalizations for AGE nationally, with infections occurring year-round [3, 4]. Both rotavirus vaccines have demonstrated high effectiveness against rotavirus hospitalizations in Taiwanese children [5–7], and reduction in rotavirus-associated hospitalizations after vaccine introduction was shown in a tertiary care hospital [5, 8]. However, the impact of these vaccines on population-level AGE burden has not been well characterized for Taiwan as a whole, and vaccine impact data are limited from Asia [9]. These data are important to better understand the effect of vaccination on morbidity burden and healthcare utilization, and may inform decisions about whether or not to include rotavirus vaccine in the national immunization program. In this report, we analyze differences in national AGE- and rotavirus-associated pediatric hospitalization rates before and after vaccine introduction.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the US Centers for Disease Control and Prevention (CDC).

CONFLICT OF INTEREST

No authors declare any conflicts of interest.

Material and Methods

Data Sources

Aggregated data on pediatric hospitalizations in Taiwan with diagnostic codes for acute gastroenteritis (AGE), rotavirus, and bronchiolitis (comparison group) were sourced from the National Health Insurance Research database (NHIRD), which captures data from the National Health Insurance program [10]. This program covers 99.9% of Taiwan's population and includes all medically necessary care [11]. Data were abstracted for 2001 – 2017 (the latest data year available) and summarized by month, year, and age group (< 12 months, 12 – 23 months, 24 – 59 months, and the overall age group of < 59 months). Hospitalizations were categorized based on International Classification of Diseases, Clinical Modification (ICD-CM) codes (9^{th} and 10^{th} revisions). Population data for Taiwan was sourced from the Department of Household Registration Affairs, Ministry of the Interior [12]. Rotavirus vaccine coverage was estimated based on administrative data as reported by healthcare providers to Taiwan Centers for Disease Control [13].

Statistical Methods

Rotavirus ICD codes that were implemented in 1998 were rarely used before mid-2003; therefore, the analysis period for modeling encompassed mid-2003 – 2017. As both vaccines were licensed in late 2006, the "pre-vaccine" period was defined as mid-2003 through mid-2006. Due to the pronounced seasonality observed in Taiwan, data were stratified by season, where rotavirus season was defined as December – May. Data were summarized by season, age group, and year, and post-vaccine rates were compared to pre-vaccine rates using Poisson regression models (exposure = year) with a log link and an offset calculated as the log of the population denominator (based on mid-year estimates). As a sensitivity analysis, rate ratios were also calculated for bronchiolitis hospitalizations across the same time period, for the age group 12 – 23 months; this age group was chosen because it is one where we would expect rotavirus to decline following vaccine introduction, but would not expect similar declines in bronchiolitis (although some interventions against respiratory syncytial virus were implemented during this time period, they would only be relevant to children < 12 months of age). Full-year estimates (not stratified by season) are presented as a supplemental analysis.

Ethics

This activity was not considered human subjects research as no interaction with subjects by investigators occurred and all data were fully deidentified prior to analysis. The institutional review board of the National Health Research Institutes approved this study (EC1051101-R5).

Results

Full-series rotavirus vaccine coverage among children <5 years was <5% for 2006 and 2007 but increased each year and reached 41% in 2014, the last year for which national data were available (Supplemental Table 1, Figure). Rotavirus-coded hospitalizations displayed a marked seasonal pattern (Figure). Children aged 12 – 23 months experienced the highest

rates of rotavirus-coded hospitalizations. Yearly peaks varied by year but were notably smaller starting in 2012. The estimated full-series rotavirus vaccine coverage for 2012 was 32% among children <5 years and 41% for children <1 year. An estimated 37% of children <5 years and 46% of children <1 year had received at least one dose (Supplemental Table 1).

Poisson regression showed that the overall rates of rotavirus hospitalizations were significantly lower in rotavirus seasons following vaccine introduction as compared to pre-vaccine rotavirus seasons: among children < 12 months of age, the rate ratio (RR) was 0.58 (95% Confidence Interval [CI]: 0.56 – 0.61); among children 12 – 23 months of age it was 0.62 (95% CI: 0.60 – 0.64); and among children 24 – 59 months of age it was 0.92 (95% CI: 0.90 – 0.95). (Table.) In comparison, the RR for bronchiolitis hospitalizations among children 12 – 23 months of age comparing post-vaccine rotavirus seasons to pre-vaccine rotavirus seasons was 0.78 (95% CI: 0.76 – 0.79), both closer to the null and with non-overlapping confidence intervals compared to the rotavirus hospitalization RR (Supplemental Table 2). AGE hospitalization RRs were closer to the null than rotavirus hospitalization RRs and had confidence intervals that were non-overlapping with rotavirus hospitalization RR confidence intervals for age groups < 12 months and 12 – 23 months of age (Supplemental Table 3).

When RRs were calculated for each year following rotavirus vaccine availability, a decline in rotavirus hospitalization RRs was observed over the analysis period, with a notable drop beginning in 2012 (Table). Yearly AGE hospitalization RRs also declined over the analysis period, but without a similar breakpoint at 2012. Similarly, yearly RRs for bronchiolitis hospitalizations in children 12 – 23 months of age experienced a smoother decline than rotavirus hospitalization RRs in the same age group, and did not exhibit a sudden drop in 2012 (Supplemental Table 2). Full-year RRs (not stratified by season) for rotavirus and AGE hospitalizations following rotavirus vaccine availability also tended to decrease over the analysis period, but these decreases were smaller in magnitude when compared with decreases during the rotavirus season.

Discussion

In this report, we describe trends in rotavirus-associated pediatric hospitalizations in Taiwan over a 14-year time period, from mid-2003 through 2017, with decreases following the implementation of rotavirus vaccine in 2006. Overall, rotavirus-associated hospitalization rates during the rotavirus season in the post-vaccination period decreased by 24% among all children <5, and by 38% among children 12 – 23 months of age, the age group most affected by rotavirus. The magnitude of the observed declines in rotavirus-coded hospitalizations is consistent with vaccine coverage of up to 40% and vaccine efficacy of >90% reported in clinical trials and observational studies in Taiwan [7, 13–16]. The present findings, using NHIRD data representing nearly the entire pediatric population of Taiwan, expand upon previous evidence from Taiwan suggesting that rotavirus vaccine has had measurable impact on rotavirus-associated pediatric hospitalizations, despite the fact that the vaccine is not part of the national immunization schedule [5, 7, 8, 16].

Although decreases in pediatric all-cause AGE hospitalizations occurred gradually over the analysis period, the decreases in rotavirus-associated hospitalizations appeared more suddenly, beginning in 2012. Notably, this pattern was seen across all age groups, and seems unlikely to be caused only by changes in care-seeking given the more gradual changes seen in all-cause AGE and bronchiolitis-associated hospitalizations. The reason for this sudden change in rotavirus-associated hospitalizations is unclear. However, it is consistent with previous research in a Taiwanese hospital showing minimal impact of rotavirus vaccination through 2011, and greater impact in 2012 and beyond [5, 8]. It is possible that the emergence of a novel GII.4 norovirus in Taiwan in 2012 [17] may have affected care-seeking and pathogen circulation for AGE. Modeling studies have suggested that annual rotavirus patterns are responsive to vaccine coverage in the population [18], as well birth rates [19, 20], with particular sensitivity when birth rates and transmission rates are low (crude birth rate <10 per 1000 and $R_0 < 30$) [19]. In Taiwan, crude birth rates remained ~8 – 9 per 1000 each year during the analysis period, with the exceptions of 2010 (7.2 per 1000) and 2012 (9.9 per 1000) [21]. In 2012, the overall full-series vaccination coverage in children <5 years of age also reached 32% (37% of children <5 years had received at least 1 dose). It could be that these trends together affected overall rotavirus hospitalization rates, perhaps reaching a threshold which interrupted transmission patterns. Interestingly, in Hong Kong, where rotavirus vaccines also became available on the private market in 2006, no decreases in rotavirus hospitalization rates were documented through the first quarter of 2011 [22]—similar to patterns seen in our analysis. However, results from a vaccine effectiveness analysis in 2014 – 2015 demonstrated high effectiveness and suggested that rotavirus hospitalization rates had decreased in Hong Kong since vaccine introduction [23].

The findings in this report are subject to the following limitations. First, because rotavirus testing (and, accordingly, use of rotavirus diagnostic codes) in Taiwan was rare before 2003, the “pre-vaccine” period in the analysis was limited to the three years from mid-2003 through mid-2006, which included one year (2005) with a notably lower rotavirus seasonal peak as compared to surrounding years. It is possible that this could have deflated estimates of rotavirus hospitalization rates in the pre-vaccine period, which in turn could have led to underestimates of rotavirus vaccine impact. Second, due to changes in data management, the authors were able to obtain population-wide vaccination coverage estimates only through 2014. However, an analysis of rotavirus vaccine effectiveness in Taiwan using surveillance from 10 sentinel hospitals during 2014 through 2017 found full-series vaccine coverage among non-AGE controls to be >60% [16], increased from 27% in a previous study conducted during 2009 – 2011 in a subset of the same hospitals [7]. Although these studies and estimates are not directly comparable to the present analysis, the trend suggests that national rotavirus vaccine coverage continued to increase after 2014. Third, due to the ecological design of this analysis, it is not possible to fully account for the effect of any secular changes that may have occurred during the study period. For instance, concurrent declines were also observed in all-cause AGE hospitalizations across all age groups, as well as in bronchiolitis hospitalizations in children 12 – 23 months of age, possibly indicating changes in healthcare utilization over time. However, these declines showed a different pattern from and were less dramatic than those seen for rotavirus-associated

hospitalizations, suggesting that at least some proportion of the decline in rotavirus activity was associated with vaccination. Further, declines were most notable during the rotavirus season, as compared to outside the season, again suggesting a rotavirus-specific effect rather than merely a global secular change. Additionally, the authors are unaware of any changes in healthcare policy that would have affected healthcare seeking or diagnostic coding behaviors.

Conclusions

In summary, rotavirus-associated pediatric hospitalizations during the rotavirus season have decreased in Taiwan following the introduction of rotavirus vaccine on the private market in 2006. Declines were most notable beginning in 2012, raising the possibility of influence by population vaccine coverage. Hospitalization rates for rotavirus-associated AGE should be continually assessed as rotavirus vaccination coverage increases in Taiwan.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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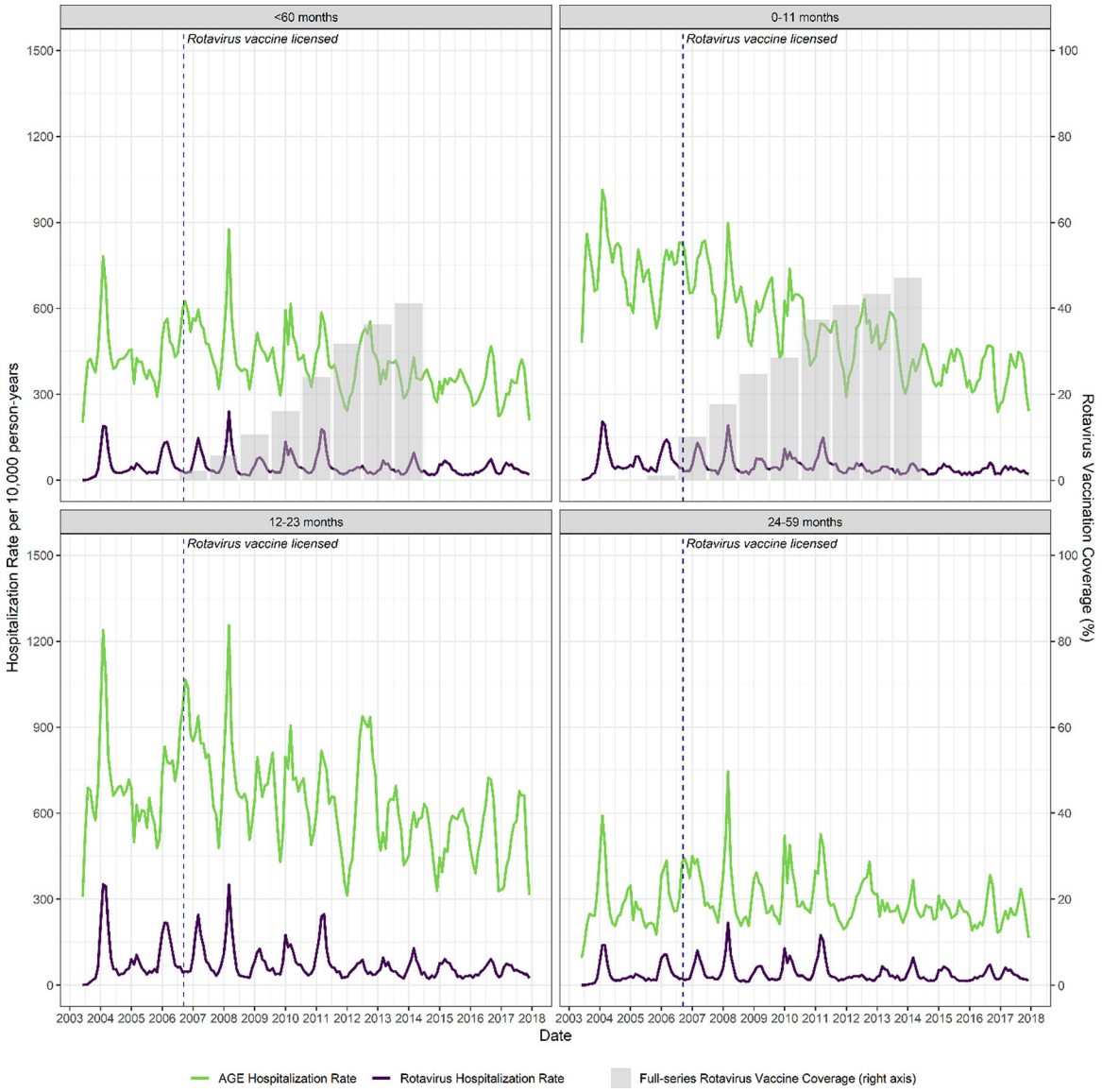

Figure: Acute Gastroenteritis and Rotavirus-Coded Hospitalization Rates per 10,000 Children, by Age Group, with Vaccination Coverage in Children <60 months and Children 0–11 months of age—Taiwan NHIRD, June 2003 – December 2017.

NHIRD: National Health Insurance Research Database. The date at which rotavirus vaccine became available is indicated by the dotted vertical line. Vaccination coverage for age groups 12 – 23 months and 23 – 59 months could not be calculated based on available data.

Table:

Rates per 10,000 Person-Years and Rate Ratios (RR) for Rotavirus-Coded Hospitalization Rates in Children < 5 Years of Age, by Age Group and Year, During the Rotavirus Season* – mid-2003 – 2017, Taiwan

Age group/year	n	Person-years	Rate (95% CI)	RR (95% CI)	p-value
0–11 months					
Pre-vaccine (mid-2003 - mid-2006)	**3054**	**306,466**	**99.65 (96.18,103.25)**	**ref**	**--**
2007	839	96,227	87.19 (81.49,93.29)	0.87 (0.81,0.94)	0.0006
2008	952	94,897	100.32 (94.14,106.9)	1.01 (0.94,1.08)	0.8574
2009	582	92,542	62.89 (57.98,68.21)	0.63 (0.58,0.69)	<.0001
2010	668	84,971	78.62 (72.87,84.81)	0.79 (0.73,0.86)	<.0001
2011	779	86,181	90.39 (84.26,96.97)	0.91 (0.84,0.98)	0.0151
2012	409	101,597	40.26 (36.54,44.35)	0.4 (0.36,0.45)	<.0001
2013	392	100,672	38.94 (35.27,42.99)	0.39 (0.35,0.43)	<.0001
2014	405	95,755	42.3 (38.37,46.62)	0.42 (0.38,0.47)	<.0001
2015	430	100,200	42.91 (39.04,47.17)	0.43 (0.39,0.48)	<.0001
2016	257	99,599	25.8 (22.83,29.16)	0.26 (0.23,0.29)	<.0001
2017	344	95,079	36.18 (32.55,40.21)	0.36 (0.32,0.41)	<.0001
2007–2017	**6057**	**1,047,718**	**57.81 (56.37,59.29)**	**0.58 (0.56,0.61)**	**<.0001**
12–23 months					
Pre-vaccine (mid-2003 - mid-2006)	**5209**	**339,574**	**153.4 (149.29,157.62)**	**ref**	**--**
2007	1578	103,625	152.28 (144.95,159.98)	0.99 (0.94,1.05)	0.7991
2008	1808	102,995	175.54 (167.64,183.82)	1.14 (1.08,1.21)	<.0001
2009	973	101,060	96.28 (90.42,102.52)	0.63 (0.59,0.67)	<.0001
2010	1156	98,418	117.46 (110.88,124.43)	0.77 (0.72,0.82)	<.0001
2011	1376	90,963	151.27 (143.49,159.48)	0.99 (0.93,1.05)	0.6449
2012	458	92,425	49.55 (45.22,54.31)	0.32 (0.29,0.36)	<.0001
2013	712	109,505	65.02 (60.42,69.98)	0.42 (0.39,0.46)	<.0001
2014	866	108,722	79.65 (74.52,85.14)	0.52 (0.48,0.56)	<.0001
2015	737	102,958	71.58 (66.6,76.94)	0.47 (0.43,0.5)	<.0001
2016	376	107,562	34.96 (31.6,38.67)	0.23 (0.21,0.25)	<.0001
2017	592	106,547	55.56 (51.26,60.22)	0.36 (0.33,0.39)	<.0001
2007–2017	**10,632**	**1,124,777**	**94.53 (92.75,96.34)**	**0.62 (0.6,0.64)**	**<.0001**
24–59 months					
Pre-vaccine (mid-2003 - mid-2006)	**7482**	**1,166,461**	**64.14 (62.71,65.61)**	**ref**	**--**
2007	2478	336,531	73.63 (70.79,76.59)	1.15 (1.1,1.2)	<.0001
2008	3197	321,806	99.35 (95.96,102.85)	1.55 (1.49,1.61)	<.0001
2009	1727	313,490	55.09 (52.55,57.75)	0.86 (0.82,0.9)	<.0001
2010	2435	308,175	79.01 (75.94,82.22)	1.23 (1.18,1.29)	<.0001
2011	3088	303,127	101.87 (98.34,105.53)	1.59 (1.52,1.66)	<.0001
2012	777	291,147	26.69 (24.88,28.63)	0.42 (0.39,0.45)	<.0001
2013	1214	282,482	42.98 (40.63,45.46)	0.67 (0.63,0.71)	<.0001
2014	1589	293,544	54.13 (51.53,56.86)	0.84 (0.8,0.89)	<.0001

Age group/year	n	Person-years	Rate (95% CI)	RR (95% CI)	p-value
2015	1525	311,239	49 (46.6,51.52)	0.76 (0.72,0.81)	<.0001
2016	740	321,719	23 (21.4,24.72)	0.36 (0.33,0.39)	<.0001
2017	1331	319,740	41.63 (39.45,43.93)	0.65 (0.61,0.69)	<.0001
2007–2017	**20,101**	**3,402,998**	**59.07 (58.26,59.89)**	**0.92 (0.9,0.95)**	**<.0001**
<60 months					
Pre-vaccine (mid-2003 - mid-2006)	**15,745**	**1,812,501**	**86.87 (85.52,88.24)**	**ref**	**--**
2007	4895	536,382	91.26 (88.74,93.85)	1.05 (1.02,1.08)	0.0026
2008	5957	519,698	114.62 (111.75,117.57)	1.32 (1.28,1.36)	<.0001
2009	3282	507,092	64.72 (62.55,66.97)	0.75 (0.72,0.77)	<.0001
2010	4259	491,563	86.64 (84.08,89.28)	1 (0.96,1.03)	0.8796
2011	5243	480,271	109.17 (106.25,112.16)	1.26 (1.22,1.3)	<.0001
2012	1644	485,169	33.89 (32.29,35.56)	0.39 (0.37,0.41)	<.0001
2013	2318	492,659	47.05 (45.17,49.01)	0.54 (0.52,0.57)	<.0001
2014	2860	498,020	57.43 (55.36,59.57)	0.66 (0.64,0.69)	<.0001
2015	2692	514,396	52.33 (50.39,54.35)	0.6 (0.58,0.63)	<.0001
2016	1373	528,880	25.96 (24.62,27.37)	0.3 (0.28,0.32)	<.0001
2017	2267	521,366	43.48 (41.73,45.31)	0.5 (0.48,0.52)	<.0001
2007–2017	**36,790**	**5,575,492**	**65.99 (65.31,66.66)**	**0.76 (0.75,0.77)**	**<.0001**

* Rotavirus season is defined as December – May.