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Rotavirus vaccination in a Medicaid infant population from four US states: compliance, vaccination completion rate, and predictors of compliance

Michaela Calnan^a, Girishanthi Krishnarajah^{b,c}, Mei Sheng Duh^a, Batool A. Haider^a, Sander Yermakov^a, Matthew Davis^a, and Songkai Yan^b

^aAnalysis Group, Inc., Boston, MA, USA; ^bGSK Vaccines, Philadelphia, PA, USA; ^cPresent address: CSL, King of Prussia, PA, USA

ABSTRACT

A retrospective observational cohort study was conducted using Medicaid administrative claims data from four states in the United States (US) to analyze overall and state-specific compliance and completion rates for rotavirus (RV) vaccines. Compliance was based on an infant receiving the recommended number of doses each within the appropriate time frame, and completion was based on an infant receiving the recommended number of doses over a recommended time period. Compliance and completion were defined separately for RV vaccines by package insert (PI) and Advisory Committee on Immunization Practices (ACIP) guidelines. Infants born between 1 May 2008 and 31 October 2011 in Florida, 31 July 2012 in Iowa and Kansas, and 30 April 2013 in Mississippi, and continuously enrolled in Medicaid with medical and pharmacy benefits for ≥ 8 months from birth were included. Study participants were assigned to cohorts based on type of RV vaccinations received within recommended vaccination windows. Using the PI guidelines, there were 658,219 eligible infants; 40% received no RV vaccines. The RV1 cohort had a significantly higher proportion of compliant infants compared to the RV5 cohort (54% vs. 25%; $p < 0.001$). For infants initiating RV1, 55% completed both doses; for infants initiating RV5, 44% completed all three doses ($p < 0.001$). Analysis by state and by ACIP guidelines yielded similar trends. Major predictors of compliance to RV vaccination were use of RV1 vaccine and DTaP vaccination completion. Increased awareness to the importance and timeliness of vaccination is needed.

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Introduction

Prior to the availability of rotavirus (RV) vaccine in 2006, RV was responsible for more than 400,000 doctor visits, 200,000 emergency room visits, 55,000 to 70,000 hospitalizations, and 20 to 60 deaths each year among children in the United States (US) younger than five years.¹ Two RV vaccines are currently approved in the US: *RotaTeq* (RV5, Merck & Co, Inc.) was approved in February 2006 as a three-dose series, and *Rotarix*TM (RV1, GSK Vaccines) was approved in April 2008 as a two-dose series. The schedules from the 2009 Advisory Committee on Immunization Practices (ACIP) recommendation for routine RV vaccination and from the package insert (PI) for RV5 and RV1 appear in Table 1.²

RV disease burden is higher among children covered by the Medicaid programs compared to those covered by commercial health plans.³ Differences in vaccine compliance and completion between the two populations may contribute to this. Compliance and completion have also varied by vaccine type. In a recent study in commercial health plans in 2009, a significantly greater proportion of infants in the RV1 cohort completed the series and was compliant to both PI and ACIP recommended guidelines as compared to the RV5 cohort.⁴ Similar findings were reported from another study among infants enrolled in a commercial health plan.⁵

A study conducted in the Truven Health MarketScan Multi-State Medicaid database from 2008 to 2012, using data from

10–13 anonymous states, demonstrated suboptimal compliance among enrolled infants.⁶ Among those following the PI guidelines, compliance and completion were significantly higher for the RV1 cohort infants as compared to the RV5 cohort. Compliance and completion to ACIP guidelines were also significantly higher in the RV1 cohort.

Medicaid is the main public health insurance program for the low-income population in the US, covering 16% of the total US population for the years 2011–2012.⁷ In June 2013, more than 28 million children were enrolled in Medicaid.⁸ The US federally funded Vaccines for Children (VFC) program provides vaccines to Medicaid enrolled children at no cost. Under this program, the Center for Disease Control (CDC) acquires vaccines at a discount and distributes them to grantees across states who in turn distribute the vaccines to registered VFC providers at no cost. The Medicaid program pays the vaccine administration fee as well.⁹ In order to be reimbursed, providers must bill the vaccine code, even though they will not be reimbursed for the vaccine itself, in addition to the appropriate administration code.¹⁰

Medicaid and other public programs provide insurance to a significant proportion of children in the US, though the enrollment varies considerably by race: more than half of Hispanic and non-Hispanic Black children in the US are enrolled in Medicaid or another public program, and approximately one quarter of Asian and non-Hispanic White children in the

Table 1. Rotavirus vaccination dosing schedules.

	RV1	PI guidelines	RV5	ACIP guidelines RV1/RV5/Mixed
Minimum age for 1 st dose	6 weeks	6 weeks	6 weeks	6 weeks
Maximum age for any dose	24 weeks	32 weeks	32 weeks	8 months and 0 days
Dose 1	Age 6 weeks through 20 weeks	Age 6 weeks through 12 weeks	Age 6 weeks through 12 weeks	Age 6 weeks through 14 weeks and 6 days
Dose 2	≥4 weeks after the previous dose	4–10 weeks after the previous dose	4–10 weeks after the previous dose	≥4 weeks after the previous dose
Dose 3	N/A	4–10 weeks after the previous dose	4–10 weeks after the previous dose	≥4 weeks after the previous dose

PI, package insert; ACIP, Advisory Committee on Immunization Practices; RV1, *Rotarix*TM, GSK Vaccines; RV5, *RotaTeq*, Merck & Co., Inc.; N/A, not applicable.

US are enrolled in these programs.¹¹ There are also variations in Medicaid programs across states as states have the ability to expand Medicaid above what is required by the federal government. States may also have distinct guidelines on how care is delivered and how providers are reimbursed. These policy decisions along with variation in public service needs and the markets in which individual state programs operate can lead to variation in Medicaid programs by state.¹² The current study uses Medicaid databases from four states to estimate RV vaccination compliance and completion overall and by state as provision of Medicaid may vary by state. The current study also evaluates the proportion of unvaccinated infants and predictors of compliance to the PI dosing guidelines while adjusting for state.

Results

Analysis by PI guidelines

A total of 658,219 infants met the inclusion criteria; infants who received more than one brand of vaccine in the 32 weeks

following birth were excluded from the analysis by PI guidelines according to the pre-established study cohort inclusion criteria. Approximately 7% of the study population had at least one claim for RV1 by 24 weeks of age (*RV1* cohort; $n = 47,766$), and 52% had at least one claim for RV5 by 32 weeks of age (*RV5* cohort; $n = 345,191$). Forty per cent had neither RV1 nor RV5 claims (*None* cohort; $n = 265,262$) (**Table 2**). Within each state, a higher proportion of infants were in the *RV5* vs. *RV1* cohort (Florida: 44% vs. 6%; Iowa: 56% vs. 7%; Kansas: 56% vs. 14%; Mississippi: 70% vs. 8%). Infants without RV1 or RV5 claims were 50% in Florida, 37% in Iowa, 29% in Kansas and 22% in Mississippi (state data not shown in tables). About 35% of the infants under fee-for-service (FFS) received no vaccination. Forty six per cent of Hispanic infants received no vaccination, whereas, 37% and 39% of White and Black infants, respectively, received none.

Of infants who received either RV1 or RV5, 29% were compliant, and compliance increased over time from 26% in 2008 to 32% in 2012 (**Table 3**). Infants in the *RV1* vs. *RV5* cohort were significantly more compliant (54% vs. 25%; $p < 0.001$). Compliance for infants in the *RV1* cohort

Table 2. Baseline demographic characteristics for vaccination cohorts for analysis by PI guidelines.

Demographic characteristic	Total	RV1 cohort	RV5 cohort	p-value RV1 vs. RV5	No RV vaccine cohort	p-value RV1 vs. RV5 vs. No RV vaccine
n (row %)	658,219 (100)	47,766 (7.3)	345,191 (52.4)	N/A	265,262 (40.2)	N/A
Birth year, n (row %/column %)				<0.0001		<0.0001
2008	88,644 (100 / 13.5)	1,312 (1.5 / 2.7)	50,643 (57.1 / 14.7)		36,689 (41.4 / 13.8)	
2009	165,700 (100 / 25.2)	11,758 (7.1 / 24.6)	87,465 (52.8 / 25.3)		66,477 (40.1 / 25.1)	
2010	183,985 (100 / 28.0)	11,689 (6.4 / 24.5)	93,644 (50.9 / 27.1)		78,652 (42.7 / 29.7)	
2011	164,279 (100 / 25.0)	15,583 (9.5 / 32.6)	81,660 (49.7 / 23.7)		67,036 (40.8 / 25.3)	
2012	47,164 (100 / 7.2)	6,307 (13.4 / 13.2)	27,706 (58.7 / 8.0)		13,151 (27.9 / 5.0)	
2013	8,447 (100 / 1.3)	1,117 (13.2 / 2.3)	4,073 (48.2 / 1.2)		3,257 (38.6 / 1.2)	
Sex, n (row %/column %)				0.4288		<0.0001
Male	335,712 (100 / 51.0)	24,138 (7.2 / 50.5)	175,105 (52.2 / 50.7)		136,469 (40.7 / 51.4)	
Female	322,507 (100 / 49.0)	23,628 (7.3 / 49.5)	170,086 (52.7 / 49.3)		128,793 (39.9 / 48.6)	
Race, n (row %/column %)				<0.0001		<0.0001
White	229,024 (100 / 34.8)	20,055 (8.8 / 42.0)	123,225 (53.8 / 35.7)		85,744 (37.4 / 32.3)	
Black	196,257 (100 / 29.8)	13,538 (6.9 / 28.3)	105,414 (53.7 / 30.5)		77,305 (39.4 / 29.1)	
Hispanic ¹	120,534 (100 / 18.3)	6,039 (5.0 / 12.6)	59,000 (48.9 / 17.1)		55,495 (46.0 / 20.9)	
Other/Unknown	112,404 (100 / 17.1)	8,134 (7.2 / 17.0)	57,552 (51.2 / 16.7)		46,718 (41.6 / 17.6)	
State, n (row %/column %)				<0.0001		<0.0001
Florida	369,147 (100 / 56.1)	21,209 (5.7 / 44.4)	163,257 (44.2 / 47.3)		184,681 (50.0 / 69.6)	
Iowa	78,643 (100 / 11.9)	5,730 (7.3 / 12.0)	44,108 (56.1 / 12.8)		28,805 (36.6 / 10.9)	
Kansas	70,491 (100 / 10.7)	10,201 (14.5 / 21.4)	39,538 (56.1 / 11.5)		20,752 (29.4 / 7.8)	
Mississippi	139,938 (100 / 21.3)	10,626 (7.6 / 22.2)	98,288 (70.2 / 28.5)		31,024 (22.2 / 11.7)	
Health insurance type, n (row %/column %)				<0.0001		<0.0001
FFS	406,822 (100 / 61.8)	28,325 (7.0 / 59.3)	236,479 (58.1 / 68.5)		142,018 (34.9 / 53.5)	
Other/Unknown	251,397 (100 / 38.2)	19,441 (7.7 / 40.7)	108,712 (43.2 / 31.5)		123,244 (49.0 / 46.5)	

PI, package insert; RV1, *Rotarix*TM, GSK Vaccines; RV5, *RotaTeq*, Merck & Co, Inc.; N/A, not applicable; FFS, Fee-for-service.¹ Kansas claims data did not specifically identify Hispanic individuals.

increased from 45% in 2008 to 65% in 2012, while compliance in the *RV5* cohort remained consistently around 25% throughout the years. A significantly higher proportion of infants in the *RV5* vs. *RV1* cohort were non-compliant with the first dose (19% vs. 3%; $p < 0.001$), but a slightly higher proportion of infants in the *RV1* vs. *RV5* cohort were non-compliant with the second dose (43% vs. 40%, $p < 0.001$). Iowa had the highest proportion of compliant infants (35%), followed by Kansas and Mississippi (33%) and then Florida (24%). The state-specific results also demonstrated that, for every state, the *RV1* cohort had a higher proportion of compliant infants compared to the *RV5* cohort (Florida: 40% vs. 22%; Iowa: 67% vs. 30%; Kansas: 61% vs. 25%; Mississippi 70% vs. 29%; $p < 0.001$ for all comparisons) (state data not shown in tables).

For the total study population, 45% of infants who received at least one RV vaccine completed all doses (Table 3). The *RV1* cohort had a significantly higher proportion of infants that completed all doses compared to the *RV5* cohort (55% vs. 44%; $p < 0.001$). State-specific results

were similar where 36% to 55% of infants who received at least one RV vaccine completed all doses, and the *RV1* cohort had a significantly higher proportion of infants that completed all doses compared to the *RV5* cohort (Florida: 40% vs. 36%; Iowa: 67% vs. 52%; Kansas: 61% vs. 44%; Mississippi: 70% vs. 54%; $p < 0.001$ for all comparisons) (state data not shown in tables). The proportion of infants who completed all doses increased from 46% in 2008 to 65% in 2012 for infants in the *RV1* cohort. For the infants in the *RV5* cohort, the proportion completing all doses was 44% or 45% in 2008 to 2012.

For all infants in the PI study population, 68% received at least one dose of diphtheria-tetanus-pertussis (DTaP) vaccination, and only 33% completed DTaP vaccination (Table 3). In both the *RV1* and *RV5* cohorts, 99% of infants received DTaP vaccination while the *RV5* cohort had a slightly higher proportion of infants completing DTaP vaccination as compared to *RV1* cohort (52% vs. 48%; $p < 0.001$).

Table 4 presents results for the multivariate analysis evaluating predictors of compliance. Infants who completed

Table 3. Rotavirus vaccination compliance and completion per PI guidelines.¹

	Total (n = 658,219)	All RV vaccinated (n = 392,957)	RV1 cohort (n = 47,766)	RV5 cohort (n = 345,191)	p-value RV1 vs. RV5
Compliance					
Infants fully compliant, n (%) ²	113,619 (17.3)	113,619 (28.9)	26,013 (54.5)	87,606 (25.4)	<0.0001
2008	13,522 (15.3)	13,522 (26.0)	594 (45.3)	12,928 (25.5)	<0.0001
2009	28,050 (16.9)	28,050 (28.3)	5,930 (50.4)	22,120 (25.3)	<0.0001
2010	30,622 (16.6)	30,622 (29.1)	6,414 (54.9)	24,208 (25.9)	<0.0001
2011	28,915 (17.6)	28,915 (29.7)	8,321 (53.4)	20,594 (25.2)	<0.0001
2012	10,852 (23.0)	10,852 (31.9)	4,089 (64.8)	6,763 (24.4)	<0.0001
2013	1,658 (19.6)	1,658 (31.9)	665 (59.5)	993 (24.4)	<0.0001
Infants who were non-compliant, n (%)	279,338 (42.4)	279,338 (71.1)	21,753 (45.5)	257,585 (74.6)	<0.0001
Non-compliant with the first dose, n (%)	66,636 (10.1)	66,636 (17.0)	1,329 (2.8)	65,307 (18.9)	<0.0001
Non-compliant with the second dose, n (%)	158,994 (24.2)	158,994 (40.5)	20,424 (42.8)	138,570 (40.1)	<0.0001
Non-compliant with the third dose, n (%)	53,708 (8.2)	53,708 (13.7)	N/A	53,708 (15.6)	N/A
Completion					
Infants who completed all doses, n (%) ²	178,204 (27.1)	178,204 (45.3)	26,038 (54.5)	152,166 (44.1)	<0.0001
2008	23,113 (26.1)	23,113 (44.5)	597 (45.5)	22,516 (44.5)	0.4530
2009	44,360 (26.8)	44,360 (44.7)	5,937 (50.5)	38,423 (43.9)	<0.0001
2010	47,843 (26.0)	47,843 (45.4)	6,416 (54.9)	41,427 (44.2)	<0.0001
2011	43,877 (26.7)	43,877 (45.1)	8,332 (53.5)	35,545 (43.5)	<0.0001
2012	16,609 (35.2)	16,609 (48.8)	4,091 (64.9)	12,518 (45.2)	<0.0001
2013	2,402 (28.4)	2,402 (46.3)	665 (59.5)	1,737 (42.6)	<0.0001
Infants who did not complete all doses, n (%)	214,753 (32.6)	214,753 (54.7)	21,728 (45.5)	193,025 (55.9)	<0.0001
Received only the first dose, n (%)	122,561 (18.6)	122,561 (31.2)	21,728 (45.5)	100,833 (29.2)	<0.0001
Received the first and the second doses only, n (%)	92,192 (14.0)	92,192 (23.5)	N/A	92,192 (26.7)	N/A
Received DTaP vaccination, n (%) ²	446,243 (67.8)	390,200 (99.3)	47,402 (99.2)	342,798 (99.3)	0.0913
2008	62,471 (70.5)	51,361 (98.9)	1,300 (99.1)	50,061 (98.9)	0.4301
2009	113,916 (68.7)	98,520 (99.3)	11,686 (99.4)	86,834 (99.3)	0.1855
2010	119,205 (64.8)	104,676 (99.4)	11,589 (99.1)	93,087 (99.4)	0.0007
2011	107,687 (65.6)	96,663 (99.4)	15,471 (99.3)	81,192 (99.4)	0.0305
2012	37,389 (79.3)	33,843 (99.5)	6,258 (99.2)	27,585 (99.6)	0.0005
2013	5,575 (66.0)	5,137 (99.0)	1,098 (98.3)	4,039 (99.2)	0.0107
Completed DTaP vaccination, n (%) ²	218,472 (33.2)	203,149 (51.7)	22,863 (47.9)	180,286 (52.2)	<0.0001
2008	30,593 (34.5)	27,273 (52.5)	601 (45.8)	26,672 (52.7)	<0.0001
2009	56,399 (34.0)	51,843 (52.2)	5,475 (46.6)	46,368 (53.0)	<0.0001
2010	58,256 (31.7)	54,353 (51.6)	5,797 (49.6)	48,556 (51.9)	<0.0001
2011	52,498 (32.0)	49,855 (51.3)	7,340 (47.1)	42,515 (52.1)	<0.0001
2012	18,229 (38.7)	17,394 (51.1)	3,077 (48.8)	14,317 (51.7)	<0.0001
2013	2,497 (29.6)	2,431 (46.8)	573 (51.3)	1,858 (45.6)	0.0008

PI, package insert; RV, rotavirus; RV1, *Rotarix*TM, GSK Vaccines; RV5, *RotaTeq*, Merck & Co, Inc.; DTaP, diphtheria-tetanus-pertussis vaccination; N/A, not applicable.

¹Compliance was based on PI dosing schedules described in Table 1. Completion was defined as receipt of two doses of RV1 by 24 weeks of age (*RV1* cohort) or three doses of RV5 by 32 weeks of age (*RV5* cohort).

²Percentages shown were calculated using the number of infants born in the relevant year

DTaP vaccine were 11.82 times more likely to be compliant as compared to those who did not complete DTaP vaccination (95% confidence interval [CI] 11.56, 12.08; $p < 0.001$). Infants with FFS vs. other/unknown insurance were 1.39 times more likely to be compliant (95% CI 1.37, 1.41; $p < 0.001$), and those attending non-pediatric vs. pediatric specialties were slightly less likely to be compliant (all $p < 0.001$). For each birth year, infants in the RV1 vs. RV5 cohort were approximately twice as likely to be compliant (all $p < 0.001$). Among the RV5 cohort, there was no trend for change in compliance over time. For the RV1 cohort, compliance increased over time; compared to those born in 2008, infants born in 2012 were 1.53 times more likely to

be compliant (95% CI 1.45, 1.62; $p < 0.001$) (data not shown in table). There were some significant differences in compliance by race in some states as demonstrated by the race and state interaction terms in the model. Similar to overall results, the state-specific predictor analysis results also demonstrated significantly higher compliance in the RV1 vs. RV5 cohort; for each birth year, infants in the RV1 vs. RV5 cohort were 1.6 to 2.1 times as likely to be compliant in Florida, 2.3 to 2.6 times as likely in Iowa, 2.3 to 3.1 times as likely in Kansas and 2.3 to 2.6 times as likely in Mississippi. Consistent with the overall findings, for the RV1 cohort, infants born in later years vs. 2008 were more likely to be compliant (state data not shown in tables).

Table 4. Multivariate model predicting rotavirus vaccination compliance by PI guidelines¹.

Variable	Relative risk	95% CI	p-value
<i>Sex</i>			
Male	REF		
Female	1.006	0.998 – 1.014	0.144
<i>Health insurance type</i>			
Other/Unknown	REF		
FFS	1.388	1.366 – 1.410	<0.001
<i>Provider specialty</i>			
Pediatric	REF		
Family practice	0.917	0.901 – 0.934	<0.001
General practice	0.957	0.937 – 0.978	<0.001
Other	0.912	0.896 – 0.927	<0.001
Unknown	0.905	0.894 – 0.916	<0.001
<i>Completion of DTaP vaccination</i>			
Non-completion of DTaP	REF		
Completion of DTaP	11.816	11.560 – 12.078	<0.001
<i>Vaccine type and birth year interaction</i>			
RV1 in birth year 2008 vs. RV5 in birth year 2008	2.016	1.914 – 2.125	<0.001
RV1 in birth year 2009 vs. RV5 in birth year 2009	2.238	2.200 – 2.276	<0.001
RV1 in birth year 2010 vs. RV5 in birth year 2010	2.200	2.167 – 2.234	<0.001
RV1 in birth year 2011 vs. RV5 in birth year 2011	2.319	2.285 – 2.354	<0.001
RV1 in birth year 2012 vs. RV5 in birth year 2012	2.735	2.665 – 2.807	<0.001
RV5 in birth year 2009 vs. RV5 in birth year 2008	0.976	0.961 – 0.992	0.004
RV5 in birth year 2010 vs. RV5 in birth year 2008	1.016	1.000 – 1.032	0.049
RV5 in birth year 2011 vs. RV5 in birth year 2008	0.975	0.959 – 0.991	0.003
RV5 in birth year 2012 vs. RV5 in birth year 2008	1.130	1.105 – 1.156	<0.001
<i>Race and state interaction</i>			
Black infants in FL vs. white infants in FL	0.890	0.874 – 0.906	<0.001
Hispanic infants in FL vs. white infants in FL	0.999	0.983 – 1.015	0.863
Other/unknown infants in FL vs. white infants in FL	1.020	0.999 – 1.041	0.060
Black infants in IA vs. white infants in IA	0.871	0.809 – 0.938	<0.001
Hispanic infants in IA vs. white infants in IA	0.967	0.918 – 1.018	0.199
Other/unknown infants in IA vs. white infants in IA	0.977	0.954 – 1.001	0.057
Black infants in KS vs. white infants in KS	0.942	0.912 – 0.973	<0.001
Hispanic infants in KS ² vs. white infants in KS	—	—	—
Other/unknown infants in KS vs. white infants in KS	0.912	0.881 – 0.944	<0.001
Black infants in MS vs. white infants in MS	1.024	1.009 – 1.040	0.002
Hispanic infants in MS vs. white infants in MS	1.010	0.969 – 1.051	0.646
Other/unknown infants in MS vs. white infants in MS	1.039	0.978 – 1.103	0.218
White infants in IA vs. white infants in FL	1.000	0.976 – 1.025	0.969
White infants in KS vs. white infants in FL	1.318	1.290 – 1.347	<0.001
White infants in MS vs. white infants in FL	0.983	0.966 – 1.001	0.057
Black infants in IA vs. black infants in FL	0.979	0.911 – 1.053	0.575
Black infants in KS vs. black infants in FL	1.395	1.346 – 1.447	<0.001
Black infants in MS vs. black infants in FL	1.131	1.110 – 1.153	<0.001
Hispanic infants in IA vs. Hispanic infants in FL	0.968	0.922 – 1.017	0.202
Hispanic infants in KS ² vs. Hispanic infants in FL	—	—	—
Hispanic infants in MS vs. Hispanic infants in FL	0.994	0.954 – 1.035	0.763
Other/unknown infants in IA vs. other/unknown infants in FL	0.958	0.938 – 0.980	<0.001
Other/unknown infants in KS vs. other/unknown infants in FL	1.179	1.134 – 1.225	<0.001
Other/unknown infants in MS vs. other/unknown infants in FL	1.001	0.941 – 1.065	0.972

PI, package insert; RV, rotavirus; RV1, *Rotarix*TM, GSK Vaccines; RV5, *RotaTeq*, Merck & Co, Inc.; CI, confidence interval; REF, reference; FFS, fee-for-service; DTaP, diphtheria-tetanus-pertussis vaccination; FL, Florida; IA, Iowa; KS, Kansas; MS, Mississippi.

¹Estimates for all combinations of the vaccine type² birth year, and race² state interactions from the multivariate model are presented.

²Kansas claims data did not specifically identify Hispanic individuals.

Analysis by ACIP guidelines

Results for demographic characteristics in the analysis by ACIP guidelines were largely similar to those in the analysis by PI guidelines (Table 5).

Of infants with at least one RV vaccine, 48% were compliant (Table 6). Compliance was significantly different between *RV1*, *RV5* and the *Mixed* cohort (57% vs. 46% vs. 55%, respectively; $p < 0.001$). Similarly, significant differences in compliance between *RV1*, *RV5* and the *Mixed* cohorts within states were observed (Florida: 42% vs. 37% vs. 53%; Iowa: 71% vs. 55% vs. 56%; Kansas: 65% vs. 47% vs. 52%; Mississippi: 72% vs. 67% vs. 51%; $p < 0.001$ for all comparisons). For the total study population, 49% of infants who received at least one RV vaccine completed all doses. The proportion of infants that completed all doses increased from 47% in 2008 to 52% in 2012. The *RV1* vs. *RV5* cohort had a significantly higher proportion of infants that completed all doses (60% vs. 47%; $p < 0.001$) while 56% of infants in the *Mixed* cohort completed all doses. The state-specific results support the combined overall results. The *RV1* vs. *RV5* cohorts in each state had a significantly higher proportion of infants that completed all doses (Florida: 45% vs. 38%; Iowa: 74% vs. 56%; Kansas: 68% vs. 47%; Mississippi: 75% vs. 57%; $p < 0.001$ for all comparisons) (state data not shown in table).

Discussion

Approximately 40% of the infants in these analyses did not receive either of the RV vaccines. The proportion of

unvaccinated infants ranged from 22% in Mississippi to 50% in Florida. Among those who received the vaccine, infants receiving *RV1* were found to be significantly more compliant to both the PI and ACIP dosing schedules as compared to those receiving *RV5*. Among those who received the RV vaccine in the analysis by PI guidelines, 29% were compliant to the PI dosing schedule, and 45% of the infants completed the vaccination series. In the analysis by ACIP guidelines, 48% were compliant to the schedule, and a similar proportion completed the vaccination series. For both *RV1* and *RV5*, there was decreased compliance with each subsequent dose in the series. The state specific analyses conducted in this study showed that there was greater compliance with *RV1* vs. *RV5* across all states, and that all states had relatively low completion and compliance to RV vaccination by ACIP and PI guidelines. Compliance to PI dosing schedule was lowest in Florida (24%) and highest in Iowa (35%). The estimates from the current study are similarly low to those reported in the Truven MarketScan Medicaid study where 43% did not receive either vaccine, and among infants who received the RV vaccine 43% were compliant and 53% completed the series according to PI guidelines.⁶ This prior study, however, looked at aggregated data from 10–13 anonymous states and did not consider whether there were variations among states. The effect of decreased compliance or incomplete vaccination on vaccine effectiveness has been examined in recent studies and was not in the scope of the current study.^{13,14}

The estimates for completing the vaccination series reported in the current study are lower than the recent US National Immunization Survey (NIS) estimates. According to the 2013

Table 5. Baseline demographic characteristics for vaccination cohorts for analysis by ACIP guidelines.

Demographic characteristic	Total	RV1 cohort	RV5 cohort	p-value RV1 vs. RV5	Mixed cohort	No RV vaccine cohort	p-value RV1 vs. RV5 vs. Mixed vs. No RV vaccine cohort
n (row %)	675,963 (100)	48,724 (7.2)	345,993 (51.2)	N/A	18,192 (2.7)	263,054 (38.9)	N/A
Birth year, n (row %/column %)				<0.001			<0.001
2008	90,234 (100 / 13.3)	1,409 (1.6/2.9)	50,766 (56.3 / 14.7)		1,626 (1.8 / 8.9)	36,433 (40.4 / 13.9)	
2009	171,319 (100 / 25.3)	11,970 (7.0 / 24.6)	87,677 (51.2 / 25.3)		5,727 (3.3 / 31.5)	65,945 (38.5 / 25.1)	
2010	189,234 (100 / 28.0)	11,956 (6.3 / 24.5)	93,872 (49.6 / 27.1)		5,376 (2.8 / 29.6)	78,030 (41.2 / 29.7)	
2011	168,376 (100 / 24.9)	15,823 (9.4 / 32.5)	81,828 (48.6 / 23.7)		4,227 (2.5 / 23.2)	66,498 (39.5 / 25.3)	
2012	48,198 (100 / 7.1)	6,428 (13.3/13.2)	27,769 (57.6 / 8.0)		1,076 (2.2 / 5.9)	12,925 (26.8 / 4.9)	
2013	8,602 (100 / 1.3)	1,138 (13.2 / 2.3)	4,081 (47.4 / 1.2)		160 (1.9 / 0.9)	3,223 (37.5 / 1.2)	
Sex, n (row %/column %)				0.4732			<0.001
Male	344,770 (100 / 51.0)	24,631 (50.6)	175,507 (50.9 / 50.7)		9,310 (2.7 / 51.2)	135,322 (39.2 / 51.4)	
Female	331,193 (100 / 49.0)	24,093 (49.4)	170,486 (51.5 / 49.3)		8,882 (2.7 / 48.8)	127,732 (38.6 / 48.6)	
Race, n (row %/column %)				<0.001			<0.001
White	236,427 (100 / 35.0)	20,409 (8.6 / 41.9)	123,502 (52.2 / 35.7)		7,581 (3.2 / 41.7)	84,935 (35.9 / 32.3)	
Black	201,302 (100 / 29.8)	13,869 (6.9 / 28.5)	105,678 (52.5 / 30.5)		5,181 (2.6 / 28.5)	76,574 (38.0 / 29.1)	
Hispanic ¹	122,919 (100 / 18.2)	6,161 (5.0 / 12.6)	59,145 (48.1 / 17.1)		2,445 (2.0 / 13.4)	55,168 (44.9 / 21.0)	
Other/Unknown	115,315 (100 / 17.1)	8,285 (7.2 / 17.0)	57,668 (50.0 / 16.7)		2,985 (2.6 / 16.4)	46,377 (40.2 / 17.6)	
State, n (row %/column %)				<0.001			<0.001
Florida	376,172 (100 / 55.6)	21,614 (5.7 / 44.4)	163,650 (43.5 / 47.3)		7,180 (1.9 / 39.5)	183,728 (48.8 / 69.8)	
Iowa	80,893 (100 / 12.0)	5,853 (7.2 / 12.0)	44,214 (54.7 / 12.8)		2,308 (2.9 / 12.7)	28,518 (35.3 / 10.8)	
Kansas	74,024 (100 / 11.0)	10,464 (14.1 / 21.5)	39,661 (53.6 / 11.5)		3,646 (4.9 / 20.0)	20,253 (27.4 / 7.7)	
Mississippi	144,874 (100 / 21.4)	10,793 (7.4 / 22.2)	98,468 (68.0 / 28.5)		5,058 (3.5 / 27.8)	30,555 (21.1 / 11.6)	
Health insurance type, n (row %/column %)				<0.001			<0.001
FFS	419,737 (100 / 62.1)	28,861 (6.9 / 59.2)	236,931 (56.4 / 68.5)		13,200 (3.1 / 72.6)	140,745 (33.5 / 53.3)	
Other/Unknown	256,226 (100 / 37.9)	19,863 (7.8 / 40.8)	109,062 (42.6 / 31.5)		4,992 (1.9 / 27.4)	122,309 (47.7 / 46.5)	

ACIP, Advisory Committee on Immunization Practices; *RV1*, *Rotarix*TM, GSK Vaccines; *RV5*, *RotaTeq*, Merck & Co, Inc.; N/A; not applicable; FFS, Fee-for-service

¹Kansas claims data did not specifically identify Hispanic individuals.

Table 6. Rotavirus compliance and completion per ACIP guidelines¹.

	Total (n=675,963)	All RV vaccinated (n=412,909)	RV1 cohort (n=48,724)	RV5 cohort (n=345,993)	p-value RV1 vs. RV5	Mixed cohort (n=18,192)	p-value RV1 vs. RV5 vs. Mixed
<i>Compliance</i>							
Infants fully compliant, n (%) ²	197,866 (29.3)	197,866 (47.9)	27,939 (57.3)	159,892 (46.2)	<0.0001	10,035 (55.2)	<0.0001
2008	25,080 (27.8)	25,080 (46.6)	636 (45.1)	23,574 (46.4)	0.3351	870 (53.5)	<0.0001
2009	49,882 (29.1)	49,882 (47.3)	6,387 (53.4)	40,315 (46.0)	<0.0001	3,180 (55.5)	<0.0001
2010	53,589 (28.3)	53,589 (48.2)	6,914 (57.8)	43,464 (46.3)	<0.0001	3,211 (59.7)	<0.0001
2011	48,614 (28.9)	48,614 (47.7)	8,940 (56.5)	37,452 (45.8)	<0.0001	2,222 (52.6)	<0.0001
2012	18,096 (37.5)	18,096 (51.3)	4,360 (67.8)	13,266 (47.8)	<0.0001	470 (43.7)	<0.0001
2013	2,605 (30.3)	2,605 (48.4)	702 (61.7)	1,821 (44.6)	<0.0001	82 (51.3)	<0.0001
Infants who were non-compliant, n (%)	215,043 (31.8)	215,043 (52.1)	20,785 (42.7)	186,101 (53.8)	<0.0001	8,157 (44.8)	<0.0001
Non-compliant with the first dose, n (%)	55,061 (8.1)	55,061 (13.3)	6,775 (13.9)	47,119 (13.6)	0.0848	1,167 (6.4)	<0.0001
Non-compliant with the second dose, n (%)	88,538 (13.1)	88,538 (21.4)	14,010 (28.8)	74,443 (21.5)	<0.0001	85 (0.5)	<0.0001
Non-compliant with the third dose, n (%)	71,444 (10.6)	71,444 (17.3)	N/A	64,539 (18.7)	N/A	6,905 (38.0)	<0.0001
<i>Completion</i>							
Infants who completed all doses, n (%) ²	200,628 (29.7)	200,628 (48.6)	29,207 (59.9)	161,276 (46.6)	<0.0001	10,145 (55.8)	<0.0001
2008	25,384 (28.1)	25,384 (47.2)	722 (51.2)	23,783 (46.8)	0.0011	879 (54.1)	<0.0001
2009	50,580 (29.5)	50,580 (48.0)	6,675 (55.8)	40,696 (46.4)	<0.0001	3,209 (56.0)	<0.0001
2010	54,408 (28.8)	54,408 (48.9)	7,309 (61.1)	43,856 (46.7)	<0.0001	3,243 (60.3)	<0.0001
2011	49,329 (29.3)	49,329 (48.4)	9,298 (58.8)	37,777 (46.2)	<0.0001	2,254 (53.3)	<0.0001
2012	18,300 (38.0)	18,300 (51.9)	4,486 (69.8)	13,336 (48.0)	<0.0001	478 (44.4)	<0.0001
2013	2,627 (30.5)	2,627 (48.8)	717 (63.0)	1,828 (44.8)	<0.0001	82 (51.3)	<0.0001
Infants who did not complete all doses, n (%)	212,281 (31.4)	212,281 (51.4)	19,517 (40.1)	184,717 (53.4)	<0.0001	8,047 (44.2)	<0.0001
Received only the first dose, n (%)	118,287 (17.5)	118,287 (28.6)	19,517 (40.1)	98,673 (28.5)	<0.0001	97 (0.5)	<0.0001
Received the first and the second doses only, n (%)	93,994 (13.9)	93,994 (22.8)	N/A	86,044 (24.9)	N/A	7,950 (43.7)	<0.0001
Received DTaP vaccination, n (%) ²	463,969 (68.6)	410,074 (99.3)	48,332 (99.2)	343,568 (99.3)	0.0109	18,174 (99.9)	<0.0001
2008	64,055 (71.0)	53,195 (98.9)	1,395 (99.0)	50,180 (98.8)	0.5768	1,620 (99.6)	0.0114
2009	119,527 (69.8)	104,649 (99.3)	11,892 (99.3)	87,038 (99.3)	0.3487	5,719 (99.9)	<0.0001
2010	124,451 (65.8)	110,526 (99.4)	11,846 (99.1)	93,307 (99.4)	<0.0001	5,373 (99.9)	<0.0001
2011	111,783 (66.4)	101,282 (99.4)	15,707 (99.3)	81,349 (99.4)	0.0288	4,226 (100)	<0.0001
2012	38,423 (79.7)	35,099 (99.5)	6,376 (99.2)	27,647 (99.6)	0.0002	1,076 (100)	<0.0001
2013	5,730 (66.6)	5,323 (99.0)	1,116 (98.1)	4,047 (99.2)	0.0014	160 (100)	0.0023
Completed DTaP vaccination, n (%) ²	231,578 (34.3)	216,456 (52.4)	22,898 (47.0)	180,219 (52.1)	<0.0001	13,339 (73.3)	<0.0001
2008	31,727 (35.2)	28,438 (52.9)	614 (43.6)	26,667 (52.5)	<0.0001	1,157 (71.2)	<0.0001
2009	60,538 (35.3)	56,033 (53.2)	5,474 (45.7)	46,363 (52.9)	<0.0001	4,196 (73.3)	<0.0001
2010	62,282 (32.9)	58,434 (52.5)	5,807 (48.6)	48,537 (51.7)	<0.0001	4,090 (76.1)	<0.0001
2011	55,499 (33.0)	52,895 (51.9)	7,341 (46.4)	42,484 (51.9)	<0.0001	3,070 (72.6)	<0.0001
2012	18,934 (39.3)	18,123 (51.3)	3,088 (48.0)	14,312 (51.5)	<0.0001	723 (67.2)	<0.0001
2013	2,598 (30.2)	2,533 (47.1)	574 (50.4)	1,856 (45.5)	0.0030	103 (64.4)	<0.0001

ACIP, Advisory Committee on Immunization Practices; RV, rotavirus; RV1, *Rotarix*TM, GSK Vaccines; RV5, *RotaTeq*, Merck & Co, Inc.; DTaP, diphtheria-tetanus-pertussis vaccination; N/A, not applicable.

¹Compliance was based on ACIP guidelines described in Table 1. Completion was defined as two doses of RV1 (RV1 cohort), three doses of RV5 (RV5 cohort), or three doses of RV1/RV5 (Mixed cohort) by 8 months after birth.

²Percentages shown were calculated using the number of infants born in the relevant year.

NIS, around 73% of the survey participants received either two doses of RV1 or three doses of RV5 vaccine.¹⁵ The NIS reports completion in children aged 19–35 months whereas the current study's estimates are presented for strict vaccine completion by the end of the vaccination window which is 6–8 months old. Additionally, the NIS sample includes both Medicaid and commercially insured infant populations. Studies have shown that a large proportion of commercially insured infants complete the series.^{4,5}

In the current study, infants in the RV1 cohort were significantly more likely to be compliant to the PI dosing schedule as compared to those in the RV5 cohort. These findings were consistent within each stratified state analysis as well. These findings corroborate those presented earlier in the Truven MarketScan Medicaid study and those among infants covered by commercial health plans.^{4,6} The simplified schedule of RV1 of only two doses compared to the three doses required by RV5 may contribute to the higher compliance levels. RV1 compliance was also found to increase with later calendar year while it remained steady for RV5. The increase in compliance with

RV1 could partly be attributed to the increased uptake of RV1 in routine practice after its launch in 2008 and an increase in vaccine awareness. RV5 was approved in 2006 so any rapid increase in initial uptake would have happened by early 2008.⁵ Similar to the Truven MarketScan Medicaid study, completion of DTaP vaccination was a significant predictor of compliance in the current study population.⁶ Increasing the coverage of one vaccination has been shown to increase the coverage and timeliness of the receipt of other vaccines in children.^{5,16,17} A recent study in Australia showed that the coverage for the third dose of DTaP vaccine increased after the availability of RV5.¹⁹ Overall, infants attending a pediatric practice were more compliant as compared to the other provider specialties. Racial differences were also observed in compliance to the dosing schedule in the current study although the magnitudes of association between race and compliance were considerably smaller than other significant associations.

There are several limitations of this study. First, administrative claims databases were used for this study. The main purpose of an administrative claims database is for the

reimbursement of services provided to the patients. The database may not capture detailed clinical information on all potential predictors and confounders. Second, procedure codes on medical claims were used for the identification of RV vaccine cohort. This may be subject to administrative errors (such as misclassifying RV1 for RV5 or vice versa) and omissions.

It is also important to note, as the study population consisted of infants enrolled in Medicaid programs in only four states, the findings of this study may be generalizable to populations of similar socioeconomic status only. Additionally, given the large sample size of this study, some results yielded statistically significant differences, despite the lack of meaningful differences. For example, even though a slightly higher proportion of infants in the RV1 vs. RV5 cohort were non-compliant with the second dose (43% vs. 40%, $p < 0.001$), this difference is not meaningful.

The current study which analyzed real-world data from four states' Medicaid programs demonstrated that a large proportion of infants did not receive any RV vaccination. Among those who received either RV vaccine, compliance and completion were low. A significantly higher proportion of infants receiving RV1 vs. RV5 vaccine was compliant and completed the series in the overall analysis as well as each individual state analysis. These findings cross-validate the results of a recent study by Krishnarajah et al.⁶ and add to our understating of compliance and completion of RV vaccination within states. More public health efforts and communication programs, both to the general population and health care providers, are needed to reach the *Healthy People 2020* target coverage of 80% for RV vaccination in the US.⁹

Methods

Data source

This study (GSK ID: HO-14-14379) was a retrospective observational cohort study conducted using Medicaid administrative healthcare claims data. The researchers have applied to over 30 US states for de-identified claims databases in support of Health Economics and Outcomes Research. Four states provided data that met conditions necessary for the present study. This database reflects the healthcare service use of approximately 12.7 million individuals. The medical and pharmacy claims and the enrollment data for any Medicaid beneficiaries eligible from 1 May 2008 through June 2012 in Florida, through March 2013 in Iowa and Kansas, and December 2013 in Mississippi were used; the end date for data inclusion varied by state depending on how recently updated data were provided to the researchers. The database contains the pooled healthcare experience of enrollees covered under FFS and other or unknown plans. The type of insurance is important to note because a claim may be more likely to be filed under FFS compared to other insurance types, as opposed to a real difference in insurance types. The database includes demographic and healthcare resource utilization data. Data on eligibility (by month) and service and provider types are also included.

Participant selection

Study participants included infants who were born between 1 May 2008 and 31 October 2011 in Florida, 31 July 2012 in Iowa

and Kansas, and 30 April 2013 in Mississippi, and were continuously enrolled in the Medicaid program with medical and pharmacy benefits for at least eight months from birth. A gap of one month in eligibility immediately after birth was allowed as newborns may not be enrolled in Medicaid immediately. Infants with claims for RV1 or RV5 by 6 weeks of age and no additional claims for either in the 8 months following birth were excluded.

Study cohorts

Infants were assigned to study cohorts for the analysis of RV vaccine compliance and completion by PI and ACIP guidelines. For the analysis by PI guidelines, cohorts included: *RV1*, Infants who received ≥ 1 dose of RV1 vaccine (identified by Current Procedural Terminology [CPT] code 90681) by 24 weeks of age; *RV5*, Infants who received ≥ 1 dose of RV5 vaccine (identified by CPT code 90680) by 32 weeks of age; *None*, Infants who did not receive either RV1 or RV5 before the maximum age. Infants who received more than one brand of vaccine in the 32 weeks following birth were excluded from the analysis by PI guidelines. For the analysis by ACIP guidelines, cohorts included the following according to vaccination by 8 months of age: *RV1*, Infants who received ≥ 1 dose of RV1 vaccine; *RV5*, Infants who received ≥ 1 dose of RV5 vaccine; *Mixed*, Infants who received both RV1 and RV5 vaccines; *None*, Infants who did not receive either RV1 or RV5 vaccine.

Study outcomes

Compliance was defined separately in each analysis based on receipt of vaccination in accordance with dosing schedules and recommended intervals between doses (Table 1). For the analysis by PI guidelines, completion was defined as receipt of two doses of RV1 by 24 weeks of age (*RV1* cohort) or three doses of RV5 by 32 weeks of age (*RV5* cohort). For the analysis by ACIP guidelines, completion required two doses of RV1 (*RV1* cohort), three doses of RV5 (*RV5* cohort), or three doses of RV1/RV5 (*Mixed* cohort) by 8 months after birth. For analyses by both guidelines, the proportion of infants completing the vaccination series was calculated for *RV1* and *RV5* cohorts separately, for all infants receiving at least one vaccine, and for all infants included in the study (vaccinated and unvaccinated). Vaccines administered prior to 6 weeks of age did not count toward completion. Timing of non-compliance (i.e. before or after recommend interval) was not analyzed.

Statistical analyses

Baseline demographic characteristics were summarized for the cohorts in the analyses by PI and ACIP guidelines. Descriptive statistics included frequency and proportion for the categorical variables. Statistically significant differences between various groups were assessed by chi-square tests for categorical variables.

To determine major predictors of compliance for RV vaccination in the analysis by PI guidelines, a modified Poisson regression model with a log link function was used.^{18,19} This modified approach, which is used to study binary outcomes,

presents estimates as relative risks (RRs). When a Poisson regression is applied to binary outcomes, the error for the estimated RR is overestimated. This modified approach uses a robust error variance to correctly estimate the standard errors for the RR. The primary predictors of interest were RV vaccine type, birth year, and an interaction between vaccine type and birth year. Other predictors, which were adapted from similar models in prior publications,^{4,6} included sex, race, state, health insurance type, provider specialty, and completion of DTaP vaccination which was defined as the receipt of three doses of DTaP in the 8 months following birth. An interaction term for race and state was also included. All results were presented as RRs with 95% CIs.

Significance tests were two-sided and differences were considered significant at $p < 0.05$. Statistical analyses were performed using SAS, version 9.3 software (SAS Institute Inc., Cary, NC, USA).

Trademark statements

Rotarix is a trademark of the GSK group of companies. *RotaTeq* is a trademark of Merck & Co., Inc.

Abbreviations

ACIP	Advisory Committee for Immunization Practices
CDC	Center for Disease Control
CI	confidence interval
CPT	Current Procedural Terminology
DTaP	diphtheria-tetanus-pertussis vaccine
FFS	fee-for-service
NIS	National Immunization Survey
PI	package insert
RR	relative risk
RV	rotavirus
US	United States
VFC	Vaccines for Children
WHO	World Health Organization

Disclosure of potential conflicts of interest

SY is an employee of, and holds restricted shares/stocks from, the GSK group of companies. GK was employed by the GSK group of companies at the time of the study conduct and during the development of the manuscript and is currently employed by CSL. GK also reports ownership of stock options/restricted shares from the GSK group of companies and CSL. MC, MSD and BAH are employees of Analysis Group which has received funding from the GSK group of companies to conduct the analytical work disclosed in this manuscript. Analysis Group, Inc. has also received multiple research grants from multiple pharmaceutical companies, including the GSK group of companies. SYe and MD were employees of Analysis Group, Inc. at the time of the analysis but declare no additional conflicts of interest.

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References

- [1] Parashar UD, Hummelman EG, Bresee JS, Miller MA, Glass RI. Global illness and deaths caused by rotavirus disease in children. *Emerg Infect Dis* 2003; 9:565-72; PMID:12737740; <http://dx.doi.org/10.3201/eid0905.020562>
- [2] Cortese MM, Parashar UD. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2009; 58 RR-2:1-25; PMID:19194371
- [3] Krishnarajah G, Demissie K, Lefebvre P, Gaur S, Sheng Duh M. Clinical and cost burden of rotavirus infection before and after introduction of rotavirus vaccines among commercially and Medicaid insured children in the United States. *Hum Vaccin Immunother* 2014; 10:2255-66; PMID:25424930; <http://dx.doi.org/10.4161/hv.29511>
- [4] Krishnarajah G, Davis EJ, Fan Y, Standaert BA, Buikema AR. Rotavirus vaccine series completion and adherence to vaccination schedules among infants in managed care in the United States. *Vaccine* 2012; 30:3717-22; PMID:22214886; <http://dx.doi.org/10.1016/j.vaccine.2011.12.077>
- [5] Panozzo CA, Becker-Dreps S, Pate V, Jonsson Funk M, Stürmer T, Weber DJ, Brookhart MA. Patterns of rotavirus vaccine uptake and use in privately insured US infants, 2006–2010. *Plos One* 2013; 8: e73825; PMID:24066076; <http://dx.doi.org/10.1371/journal.pone.0073825>
- [6] Krishnarajah G, Landsman-Blumberg P, Eynullayeva E. Rotavirus vaccination compliance and completion in a Medicaid infant population. *Vaccine* 2015; 33:479-86; PMID:24962753; <http://dx.doi.org/10.1016/j.vaccine.2014.06.059>
- [7] The Henry J. Kaiser Family Foundation [Internet]. United States: The Henry J. Kaiser Family Foundation; 2015. Health Insurance Coverage of the Total Population; 2015 [cited 15 Sep 2015]; [about 3 screens]. Available from: <http://kff.org/other/state-indicator/total-population/>
- [8] The Henry J. Kaiser Family Foundation [Internet]. United States: The Henry J. Kaiser Family Foundation; 2015. Medicaid Moving Forward; 2015 [cited 15 Sep 2015]; [about 10 screens]. Available from: <http://kff.org/health-reform/issue-brief/medicaid-moving-forward/>
- [9] Medicaid Keeping America Healthy [Internet]. Baltimore, Maryland, United States: Medicaid; 2015. Quality Care of Vaccines: 2015 [cited 15 Sep 2015]; [about 1 screen]. Available from: <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/quality-of-care-%E2%80%93vaccines.html>
- [10] Kansas Medical Assistance Program Provider Manual [Internet]. Kansas, United States: Kansas Medical Assistance Program. Professional Services Provider Manual [cited 8 Nov 2015]. Available from: https://www.kmap-state-ks.us/Documents/Content/Provider%20Manuals/Professional_04062010_10021.pdf
- [11] The Henry J. Kaiser Family Foundation [Internet]. United States: The Henry J. Kaiser Family Foundation; 2015. Children's Health Coverage: Medicaid, Children's Health Insurance Program and the Affordable Care Act; 2015 [cited 15 Sep 2014]; [about 7 screens]. Available from: <http://kff.org/health-reform/issue-brief/childrens-health-coverage-medicaid-chip-and-the-aca/>
- [12] The Henry J. Kaiser Family Foundation [Internet]. United States: The Henry J. Kaiser Family Foundation; 2015. Medicaid Per Enrollee Spending: Variation Across States; 2015 [cited 15 Sep 2015]; [about 10 screens]. Available from: <http://kff.org/medicaid/issue-brief/medicaid-per-enrollee-spending-variation-across-states/>
- [13] Desai SN, Esposito DB, Shapiro ED, Dennehy PH, Vazquez M. Effectiveness of rotavirus vaccine in preventing hospitalization due to

- rotavirus gastroenteritis in young children in Connecticut, USA. *Vaccine* 2010; 28(47):7501-6
- [14] Dennehy PH, Vesikari T, Matson DO, Itzler RF, Dallas MJ, Goveia M, DiNubile MJ, Heaton PM, Ciarlet M. Efficacy of the pentavalent rotavirus vaccine, RotaTeq(R) (RV5), between doses of a 3-dose series and with less than 3 doses (incomplete regimen). *Hum Vaccin* 2011; 7(5):563-8
- [15] Elam-Evans LD, Yankey D, Singleton JA, Kolasa M. Centers for Disease Control and Prevention. National, state, and local area vaccination coverage among children aged 19–35 months- United States, 2013. *MMWR Morb Mortal Wkly Rep* 2014; 63:741-8; PMID:25166924
- [16] Wendy B. Vaccination with 3-dose paediatric rotavirus vaccine (RotaTeq®): impact on the timeliness of uptake of the primary course of DTaP vaccine. *Vaccine* 2012; 30:5293-7; PMID:22575163; <http://dx.doi.org/10.1016/j.vaccine.2012.04.071>
- [17] Hull BP, Menzies R, Macartney K, McIntyre PB. Impact of the introduction of rotavirus vaccine on the timeliness of other scheduled vaccines: the Australian experience. *Vaccine* 2013; 31:1964-9; PMID:23422140; <http://dx.doi.org/10.1016/j.vaccine.2013.02.007>
- [18] Greenland S. Model-based estimation of relative risks and other epidemiological measured in studies of common outcomes and in case-control studies. *Am J Epidemiol* 2004; 160:301-5; PMID:15286014; <http://dx.doi.org/10.1093/aje/kwh221>
- [19] Zou G. A modified Poisson regression approach to prospective studies with binary data. *Am J Epidemiol* 2004; 159:702-6; PMID:15033648; <http://dx.doi.org/10.1093/aje/kwh090>