



Rotavirus vaccination compliance and completion in a Medicaid infant population



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ABSTRACT

We examined completion and compliance rates of rotavirus (RV) vaccination according to the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Food and Drug Administration approved Prescribing Information (PI) for *Rotarix*[®] (RV1, GlaxoSmithKline Vaccines) and *RotaTeq*[®] (RV5, Merck and Co.) among infants under one year of age covered by Medicaid programs. Healthcare claims data from state Medicaid programs that constituted the *Truven Health MarketScan*[®] Multi-State Medicaid Database were retrieved from May 2008–June 2012. Infants were grouped under PI and ACIP cohorts based on the dosing regimens followed. The overall compliance per PI ($n = 673,956$) and ACIP ($n = 695,612$) recommendations were 24.5% and 28.2%, respectively; completion rates were 30.3% and 32.6%, respectively. In the PI cohort, infants who received RV1 had significantly higher compliance as compared with infants who received RV5 (65.2% vs. 31.3%; $p < 0.0001$); completion rates among infants receiving RV1 and RV5 were 65.3% and 46.4%, respectively ($p < 0.0001$). In the ACIP cohort, compliance with RV1 was significantly higher than RV5 (68.8% vs. 45.9%; $p < 0.0001$) as was the overall completion rate (73.5% vs. 48.8%; $p < 0.0001$). While compliance is increasing year over year, overall compliance of RV vaccines is suboptimal, with over 40% of eligible infants unvaccinated in both populations. The 2-dose RV vaccine showed better completion rates and higher compliance than the 3-dose RV vaccine in the United States. Public health initiatives focusing on suboptimal compliance and completion rates of RV vaccination in the Medicaid population could improve these metrics, thereby offering protection against RV infection.

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1. Introduction

Rotavirus (RV) is one of the leading causes of gastroenteritis (GE) (vomiting and diarrhea) in small children less than five years of age [1]. Globally, it has been estimated that RV at one time accounted for nearly 611,000 diarrheal deaths and 39% of diarrheal hospitalizations in children aged less than five years annually [2]. Deaths in the United States (US) were estimated to be uncommon with only 20–40 occurring annually before the initiation of the RV vaccination program in 2006 [3]. However the direct costs due to RV were

estimated to be \$300 million annually with 55,000–70,000 hospitalizations, 200,000 emergency department visits, and 400,000 outpatient visits each year among children less than five years old [3]. When indirect costs were added, the total annual costs were estimated at more than \$1 billion [3].

Two vaccines are currently approved by the Food and Drug Administration (FDA) for the prevention of rotavirus gastroenteritis (RVGE) among infants in the US [4]. The oral pentavalent vaccine, *RotaTeq*[®] (RV5, Merck and Co.) was approved as a three-dose series in February 2006, and the oral monovalent vaccine, *Rotarix*[®] (RV1, GlaxoSmithKline Vaccines) was approved as a two-dose series in April 2008. In response to the approval of RV5, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination with RV5 given orally at ages two, four, and six months in 2006 [4]. However, prescribing information (PI) for RV5 states the first dose is to be given starting at 6–12 weeks of age, with the subsequent doses given at 4–10-week intervals, and the last dose should not be given after 32 weeks of age [5]. In 2009, the ACIP updated these recommendations to include vaccination with

Abbreviations: ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; CPT, Current Procedural Terminology; DTaP, diphtheria, tetanus toxoids, and acellular pertussis; FDA, Food and Drug Administration; GE, gastroenteritis; HMO, Health Maintenance Organization; NIS, National Immunization Survey; PI, prescribing information; RV, rotavirus; RVGE, rotavirus gastroenteritis; UPP, Universal Purchase Programs; US, United States.

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RV1 given orally at ages two months and four months [6]. The RV1 PI, however, states the first dose of RV1 is to be given no earlier than six weeks of age and the second (i.e., last) dose at least four weeks later, but before 24 weeks of age [7]. A study of adherence to the 2006 ACIP RV5 dosing schedules for the first three months following vaccine availability found that 51% of infants received their first dose outside the recommended age window [8]. Another study after the first six months of RV vaccine implementation found 20% of infants received their first dose outside the recommended window [9]. Recent studies also evaluated the rates of adherence (i.e., compliance) to both the ACIP and FDA-approved dosing schedules for RV1 and RV5 among infants in the US. One study included infants less than one year of age enrolled in managed care plans and initiating RV vaccination during the months January to June of 2009 [10]. Overall, 61.2% of the population were compliant with the PI dosing schedules (RV1 75.0% vs. RV5 59.5%; $p < 0.001$) and 77.2% were compliant with the ACIP dosing schedule (RV1 83.3% vs. RV5 76.4%; $p < 0.001$). Completion rate, defined as receiving all doses but not necessarily on schedule, was 84.3% (RV1 91.0% vs. RV5 83.4%; $p < 0.001$) [10]. Two recent studies on privately insured children also found higher compliance and completion rates among children receiving RV1 than those receiving RV5 [11,12].

The 2012 National Immunization Survey (NIS) released by the CDC monitored the vaccination coverage among children up through 19–35 months [13]. Significant differences were found by race (White 70.5% vs. Black 60.4%; $p < 0.05$) and poverty status (below poverty level 63.4% vs. above poverty level 71.6%; $p < 0.05$) [13]. In a large privately-insured population, between 78 and 83% of eligible infants received at least one RV vaccine per month in 2009–2010 [11]. Both Panozzo et al. [11] and Krishnarajah et al. [12] found that among infants receiving at least one rotavirus vaccine, the completion rate was higher among those receiving RV1 as compared to those receiving RV5 (Panozzo et al: 87% vs. 79%, $p < 0.01$; Krishnarajah et al: 91% vs. 83%, $p < 0.01$). There is currently no information on completion or compliance rates of RV vaccination within the Medicaid population. The purpose of the current study therefore was to examine RV vaccination completion and compliance rates with both the ACIP recommendations and FDA approved PI schedule overall and for RV1 and RV5 separately among infants less than one year of age enrolled in a large number of Medicaid programs. This study also estimated the proportion of infants who remained unvaccinated and identified the possible infant and plan level predictors of compliance with the PI.

2. Methods

2.1. Data source

This study was a retrospective observational cohort study using administrative healthcare claims data from state Medicaid programs that constituted the *Truven Health MarketScan*® Multi-State Medicaid Database for the period May 1, 2008 to June 30, 2012. The database reflects the healthcare service use (medical and pharmacy claims) of over 6.7 million individuals covered by Medicaid programs in 10–13 geographically dispersed states within a given year. Medicaid data were collected from states with and without Universal Purchase Programs (UPP). Because of confidentiality agreements, we are unable to reveal the states, but were able to identify the UPP status of the states that contributed to the database. Enrollees were those covered under fee-for-service and managed care plans, for whom monthly eligibility data, federal aid category data (i.e., income based, disability, temporary assistance for needy families) and racial information were available. Due to contractual obligations, the specific states contributing data to the database were not reported.

2.2. Study populations

Due to differences in PI and ACIP recommendations for the administration schedule of rotavirus vaccines, two separate populations of infants were defined. Separate analyses were conducted for the following cohorts: all states (i.e., both UPP and non-UPP states), and non-UPP states only. Age at the time of RV vaccination was based on the service date on the claim for the first dose and the birth date. Vaccine type was identified by the Current Procedural Terminology (CPT) codes on outpatient medical claims.

2.2.1. PI population

Infants in the PI population, born between May 1, 2008 and December 31, 2011 were identified and grouped into three cohorts:

- (1) infants with at least one claim for RV1 (RV1-PI);
- (2) infants with at least one claim for RV5 (RV5-PI); and
- (3) infants not receiving any doses of RV1 or RV5.

Eligible infants were further required to have continuous enrollment in medical and pharmacy benefits for at least 24 weeks from birth for the RV1 cohort and for at least 32 weeks from birth for the RV5 cohort. Infants who had evidence of receiving more than one brand (RV1 and RV5) of vaccine in their series were excluded from the PI cohorts. Infants who had received RV1 or RV5 before six weeks of age were also excluded.

2.2.2. ACIP population

Infants of the ACIP population selected for analysis were born between May 1, 2008 and October 31, 2011 and continuously enrolled in medical and pharmacy benefits from birth to eight months of age. Infants receiving a mixed regimen of RV vaccines (at least one dose of RV1 and one dose of RV5) were included. Four cohorts identified for the ACIP analysis were:

- (1) infants with at least one claim for RV1 and no claims for RV5;
- (2) infants with at least one claim for RV5 and no claim for RV1;
- (3) infants with claims for both RV1 and RV5 [6]; and
- (4) infants who did not have evidence of receiving either RV1 or RV5.

Infants who had received RV1 or RV5 before six weeks of age were excluded.

2.3. Compliance and completion

Compliance to each RV dose was assessed in accordance with the corresponding PI or ACIP schedules as described in Table 1. Individual infants were categorized as “compliant” if he/she received all doses in accordance with the recommended schedule.

Completion was defined as receipt of two doses of RV1, three doses of RV5, or for the ACIP-mixed cohort one dose of RV1 and two doses of RV5 in any order. Whether infants received three doses of diphtheria, tetanus toxoids, and acellular pertussis (DTaP) vaccine was also assessed. The DTaP vaccine was selected because the recommended timing overlaps with the first 2 (2 months and 4 months) or 3 (2 months, 4 months and 6 months) doses of rotavirus vaccine.

2.4. Statistical analyses

Baseline characteristics were summarized by population (PI or ACIP) and cohort (RV1, RV5, Mixed, None) using frequency and percentage for categorical variables and mean and standard deviation for continuous variables. Statistical significance was evaluated

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