

Title	Observational study to assess the effectiveness of ROTATEQ [®] against acute gastroenteritis (AGE) caused by rotavirus (regardless of type) and by type in children in China (V260-079)
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Medicinal product	Reassortant Rotavirus Vaccine, Live, Oral, Pentavalent (Vero Cell)
Joint PASS	No
Research question and objectives	This is a secondary data analysis using data previously collected for the V260-077 study. • Primary objective: To assess the effectiveness of ROTATEQ[®] against rotavirus acute gastroenteritis (RVGE) regardless of type in children treated in the hospital for AGE. • Secondary objective: To assess the type-specific effectiveness of ROTATEQ[®] against RVGE due to specific RV G-types, P-types, or G-/P- combination types in children treated in the hospital for AGE.
Country of study	China
Author	PPD Sr. Scientist, Biostatistical and Research Decision Sciences (BARDS) Epidemiology, Merck Sharp & Dohme LLC
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MARKETING AUTHORISATION HOLDER(S)

Marketing authorisation holder(s)	Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., 126 East Lincoln Ave., P.O. Box 2000, Rahway, New Jersey 07065 USA
MAH contact person	PPD

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1 ABSTRACT

Title

Observational study to assess the effectiveness of ROTATEQ[®] against acute gastroenteritis (AGE) caused by rotavirus (regardless of type) and by type in children in China (V260-079)

Keywords

Rotavirus vaccine, rotavirus gastroenteritis, G8 type, vaccine effectiveness, test-negative case-control design

Rationale and Background

ROTATEQ[®] is an oral, live pentavalent (G1, G2, G3, G4, and P1A[8]) human–bovine (WC3) reassortant rotavirus vaccine. It was approved in China on April 12, 2018, for the prevention of rotavirus acute gastroenteritis (RVGE) in infants and children caused by the types G1, G2, G3, G4, and G9. In recent years, a few regional real-world studies have demonstrated protection of ROTATEQ[®] beyond the indicated types listed on the Chinese label.

At the time of ROTATEQ[®]'s marketing authorization in China, the Center for Drug Evaluation (CDE) required to continuously observe its effectiveness against serotypes G2, G3, and G4 in a larger population. To fulfil this post-marketing requirement, study V260-077 (EU PAS No. EUPAS36666) was conducted for four RV peak seasons (October 2020 to March 2021, October 2021 to April 2022, October 2022 to April 2023, and October 2024 to April 2025) to assess the vaccine effectiveness (VE) of ROTATEQ[®] against RVGE caused by types G2/G3/G4 and G1/G2/G3/G4/G9 in children in China. During the study period, cases of RVGE in children due to types other than G1, G2, G3, G4, and G9 were observed.

This study (V260-079) leveraged the V260-077 dataset to assess the VE of ROTATEQ[®] against RVGE regardless of type, and type-specific VE against individual G types, P types, and G-/P- combinations with sufficient prevalence in the study regions during the study period.

Research Objectives and Questions

This is a secondary data analysis using data previously collected for the V260-077 study.

Primary objective: To assess the effectiveness of ROTATEQ[®] against RVGE regardless of type in children treated in the hospital for Acute Gastroenteritis (AGE).

Secondary objective: To assess the type-specific effectiveness of ROTATEQ[®] against RVGE due to specific RV G-types, P-types, or G-/P- combination types in children treated in the hospital for AGE.

Study Design

Test-negative case-control design.

Setting

The dataset was derived from the V260-077 study population, which comprised children age-eligible to be fully vaccinated with 3 doses of ROTATEQ[®] who received treatment for AGE in hospitals and had documented RV test results.

Subjects and study size

Subjects

Children from the V260-077 study dataset with documented RV test results (ELISA positive/negative) were included. Children meeting any of the following criteria were excluded from the main statistical analysis population, otherwise specified for sensitivity analyses:

- Children without collection of vaccination records
- Children vaccinated with mixed RV vaccines
- Received other RV vaccines than ROTATEQ[®]
- Children with incomplete ROTATEQ[®] schedules or vaccinated out of age-indication
- Children vaccinated with ROTATEQ[®] within 14 days before the onset of AGE

Study Size

V260-079 is a secondary analysis based on the V260-077 study database and includes the full V260-077 study population (N = 7,510).

Variables and data sources

Variables

Exposure

The exposure of interest was ROTATEQ[®] vaccination status. Children were considered “vaccinated” if they had received all 3 doses of ROTATEQ[®] following the immunization schedule approved in the Chinese label at least 14 days before AGE onset. Children were considered “not vaccinated” if they had not received any dose of ROTATEQ[®] or any other RV vaccines.

Outcomes

For the primary objective, all RVGE cases (Enzyme-Linked Immunosorbent Assay [ELISA]-positive) identified in the structured dataset were defined as “cases”.

For the secondary objective, RVGE cases attributable to individual RV G types, P types, and G/P combinations were defined as “cases”.

For both primary and secondary objectives, all RV-negative AGE cases (ELISA-negative) were defined as “controls”.

Covariates

Covariates included child’s gender, child’s onset age, residence locations, symptom onset seasons, birth seasons, study hospital regions, and clinical settings. In sensitivity analysis 3 (propensity score matching followed by conditional logistic regression) and sensitivity analysis 5, parents’ education level was included as an additional covariate.

Data Sources

This study analyzed anonymized data previously collected for the V260-077 study. No additional informed consent was required, as only anonymized data was used and no new patient information was collected. Study (V260-079) has been approved by the Ethics Committee of Beijing Children’s Hospital (approval No. [2025]-Y-185-A).

In the V260-077 study, RV vaccination history was abstracted from vaccination cards or, if unavailable, from officially authorized application programs. Clinical manifestations and demographic data were obtained from the hospital information system or through interviews. Stool samples collected per routine practice were sent to a central laboratory for testing: Group A rotavirus antigen was detected by ELISA, for ELISA-positive samples, multiplex reverse transcription–polymerase chain reaction (RT-PCR) assays were conducted for further genotyping of the strains.

Statistical analysis

Demographics, disease characteristics, vaccination status and RV types were summarized descriptively. For continuous variables, summaries included the number of participants, the number with missing data, mean, standard deviation, median, 25th percentile, 75th percentile, minimum, and maximum. For categorical variables, counts and percentages were reported for each category.

For both the primary objective and the secondary objective, crude and adjusted odds ratios (OR) for ROTATEQ[®] vaccination for cases compared to controls were estimated using univariate and multivariate logistic regression. VE was calculated as $(1 - \text{OR}) \times 100\%$, along with 95% confidence intervals (CIs) for both crude and adjusted estimates.

Covariates were compared between the cases and the controls using univariate logistic regression, and those with $P < 0.1$ were included in the unconditional multivariate logistic regression models. Adjusted OR estimates, 95% CIs, and P values were calculated for the association between ROTATEQ[®] vaccination and AGE status (RVGE regardless of types or type-specific RVGE, versus RV-negative AGE). Note that those estimates were provided only if regression models achieved convergence using the SAS 9.4 default setting.

All sensitivity analyses were separately performed for the primary endpoint and secondary endpoint, if the data were sufficient to ensure model convergence.

These sensitivity analyses were conducted to assess the reliability and robustness of VE estimates under alternative assumptions:

1. Sensitivity analysis 1: Included participants without confirmed vaccination information in the primary endpoint analysis, assuming that all children with missing vaccination data were unvaccinated.
2. Sensitivity analysis 2: Treated age of onset (in months) and symptom-onset seasons as important confounders and forced them into the unconditional multivariate logistic regression model, regardless of their P values in the univariate logistic regression, even if $P \geq 0.1$.
3. Sensitivity analysis 3: Propensity score matching (PSM) of cases with appropriate controls followed by conditional logistic regression with matching factors: age of onset (in months), gender, education level of the children's parents (college and above for either parent's education level, yes or no), and symptom onset season. For both primary and secondary endpoints, an up-to 1:3 case-to-control PSM ratio was used to allow the utmost number of matched pairs, if the number permitted.
4. Sensitivity analysis 4: PSM followed by conditional logistic regression with matching factors: age of onset (in months), gender, and symptom onset season. For both primary and secondary endpoints, an up-to 1:3 case-to-control PSM ratio was used to allow the utmost number of matched pairs, if the number permitted.
5. Sensitivity analysis 5: Included parents' education level into the multivariate model if it differed significantly between cases and controls.

Unless otherwise specified, analyses used a two-sided significance level of 0.05. Statistical programming was performed in SAS version 9.4.

Results

Primary Objective (VE against RVGE regardless of type)

Analysis Population

Among 7510 children with AGE in the dataset, 5594 were eligible for the analysis, including 1619 RVGE cases and 3975 RV-negative controls. The most common reasons for exclusion from analysis were vaccination with rotavirus vaccines other than ROTATEQ® (n=1092; 14.5%) and incomplete vaccination with ROTATEQ® (n=405; 5.4%).

Demographic Characteristics

A statistically significant difference was observed in age of onset between cases and controls ($P < 0.001$) in the univariate analysis. The median age of onset was 19.30 months (Interquartile Range [IQR]: 13.8–28.1) in cases and 14.40 months (IQR: 9.5–21.8) in controls. The majority of AGE onset occurred at 12–23 months (49.7% in cases and 41.7% in controls) and followed by ≤ 11 months (17.5% in cases and 37.3% in controls).

In both RVGE cases and controls, over 60% of AGE cases occurred in urban areas, and more than 86% were inpatients. A significant difference in residence was observed between cases and controls ($P < 0.001$).

Approximately 58% of both cases and controls were born during RV peak seasons. Among RVGE cases, AGE disease onset during the 1st (Oct 2020–Mar 2021), 2nd (Oct 2021–Apr 2022), 3rd (Oct 2022–Apr 2023), and 4th (Oct 2024–Apr 2025) peak seasons was 26.1%, 30.4%, 13.9%, and 29.6%, respectively; corresponding proportions in controls were 5.7%, 31.2%, 32.2%, and 30.9%. Significant differences were observed for the 1st and 3rd seasons (both with $P < 0.001$), compared with the 4th season.

Males comprised 60.5% of the population, with no significant gender difference between cases and controls. Being born during the RV peak season was not associated with an increased risk of RVGE. Overall, 60.8% of children had at least one parent with a college education or higher.

Significant differences were observed in covariates including age of onset ($P < 0.001$), residence location ($P < 0.001$), regions of study hospitals (Central vs East: $P = 0.034$, West vs East: $P < 0.001$) clinical settings ($P = 0.004$), symptom onset season (2020/10–2021/3 vs 2024/10–2025/4: $P < 0.001$, 2022/10–2023/4 vs 2024/10–2025/4: $P < 0.001$).

Outcome Data

Among 1619 RVGE cases, 117 (7.2%) were fully vaccinated with 3 doses of ROTATEQ®, compared with 1465 (36.9%) of 3,975 controls. The crude VE against all RVGE regardless of types was 86.7% (95% CI: 83.7–89.1). After adjusting for age at onset, residence, hospital region, clinical settings, and season of symptom onset, the adjusted VE was 82.3% (95% CI: 78.2–85.6).

Secondary Objective (VE against specific type of RVGE)

RV Type Distribution

Among 1619 RVGE cases, G9 (41.2%) and G8 (36.3%) were the predominant G-types, while P[8] was the predominant P-type (93.6%). The most frequent G-P type combinations were G9P[8] (40.3%), G8P[8] (36.1%), and G3P[8] (14.6%).

Outcome Data

The VE of ROTATEQ[®] against RVGE was assessed by RV types (G, P, and G-P combinations). Estimates were adjusted for age at onset, residence, hospital region, and season of symptom onset if these covariates differed significantly between cases and controls ($P < 0.1$).

ROTATEQ[®] VE against G1 (n=17), G2 (n=52), G3 (n=242), G8 (n=588), and G9 (n=667) were evaluated in this study. The crude and adjusted VE were 89.3% (95% CI: 19.2%–98.6%) and 88.0% (95% CI: 9.4%–98.4%) for G1; 93.2% (95% CI: 71.8%–98.3%) and 90.4% (95% CI: 59.8%–97.7%) for G2; 91.8% (95% CI: 85.0%–95.6%) and 92.2% (95% CI: 85.4%–95.8%) for G3; 79.8% (95% CI: 73.5%–84.6%) and 75.6% (95% CI: 67.9%–81.5%) for G8; and 90.2% (95% CI: 86.2%–93.1%) and 84.2% (95% CI: 77.2%–89.0%) for G9.

The study demonstrated statistically significant VE of ROTATEQ[®] against RVGE attributable to P[8] (n=1,516) and P[4] (n=63). The crude and adjusted VE were 86.7% (95% CI: 83.7%–89.2%) and 82.5% (95% CI: 78.3%–85.9%) for P[8], and 88.4% (95% CI: 68.0%–95.8%) and 85.9% (95% CI: 60.6%–94.4%) for P[4].

For the G/P combinations observed, the crude and adjusted VE estimates of ROTATEQ[®] against RVGE were as follows: G1P[8], 89.3% (95% CI: 19.2%–98.6%) and 88.0% (95% CI: 9.4%–98.4%); G2P[4], 92.7% (95% CI: 69.9%–98.2%) and 90.4% (95% CI: 60.1%–97.7%); G3P[8], 91.6% (95% CI: 84.6%–95.4%) and 92.0% (95% CI: 85.1%–95.7%); G8P[8], 80.1% (95% CI: 73.1%–84.8%) and 75.9% (95% CI: 68.2%–81.8%); and G9P[8], 90.6% (95% CI: 86.6%–93.4%) and 84.6% (95% CI: 77.6%–89.4%).

Sensitivity analysis for both primary and secondary objectives

Sensitivity analyses were performed separately for the primary endpoint and the secondary endpoint when data allowed model convergence.

For the primary endpoint, VE of ROTATEQ[®] against all RVGE regardless of type ranged from 81.7% to 85.3% and demonstrated statistically significant and consistent results under different assumptions in the sensitivity analyses. The highest VE point estimate (85.3%) was observed with a 1:3 PSM, with conditional logistic regression adjusted for age at onset (in months), gender, and symptom onset season. The lowest VE point estimate (81.7%) was observed with a 1:2 PSM, with conditional logistic regression adjusted for age of onset (in

months), gender, education level of the children's parents (college and above for either parent's education level, yes or no), and symptom onset season.

For RVGE attributable to G8, the ROTATEQ[®] VE estimates were likewise stable and statistically significant, ranging from 75.73 % to 78.19%. The lowest VE estimate (75.73%) was observed when assuming that all children with missing vaccination data were unvaccinated.

Discussion

VE against RVGE regardless of type

Vaccine effectiveness of ROTATEQ[®] against RVGE regardless of type was high (>80%) when adjusted for age at onset, residence (urban vs. rural), hospital region (central, west, east), and season of symptom onset (Oct 2020–Mar 2021; Oct 2021–Apr 2022; Oct 2022–Apr 2023; Oct 2024–Apr 2025). Sensitivity analyses that used alternative assumptions provided VE estimates ranging from 81.7% to 85.3%, confirming the reliability and robustness of the main analysis. VE findings for ROTATEQ[®] against RVGE regardless of type were consistent with clinical trial and real-world evidence in the Chinese population. A randomized, double-blind, placebo-controlled trial in healthy Chinese infants reported ROTATEQ[®] efficacy of 78.9% and 95.5% against severe RVGE by the Vesikari scoring system with a score of 11 or more, and by the Clark scoring system with a score of 17 or more, respectively, and 69.3% against RVGE of any severity. In real-world studies employing test negative case-control designs, ROTATEQ[®] vaccine effectiveness ranged from 64.1% to 85.0% against RVGE of any severity and from 81.0% to 86.6% against moderate to severe RVGE, with all adjusted estimates reaching statistical significance. The present study included patients that were either admitted to hospital for AGE or received intravenous (IV) rehydration for at least two consecutive days in outpatient settings, representing moderate-to-severe RVGE cases. Severity could not be assessed using the Vesikari or Clark scoring systems, as it was not possible to collect the relevant clinical data. Clinical setting (hospitalization vs. outpatient) was considered as a potential confounder and had been adjusted for the VE analysis.

RV circulation and VE against G8

Across four peak seasons (Oct 2020–Mar 2021, Oct 2021–Apr 2022, Oct 2022–Apr 2023, and Oct 2024–Apr 2025) in China, G9, G8, and G3 accounted for more than 90% of RVGE cases, with G8 alone responsible for 36.3%; other RV types, such as G4 or G6, accounted for only 0.2% of all RV types. The observed high prevalence of G8 is consistent with the reports by Tian et al. (2024) in Beijing and Zhou et al. (2023) in Wuhan. Therefore, reducing the risk of G8-related RVGE has significant public health implications in China.

In this study, ROTATEQ[®] protected against G8-attributable RVGE, with an adjusted VE of 75.64% (95% CI: 67.85–81.54). Sensitivity analyses confirmed the robustness of this finding, with adjusted VE estimates ranging from 75.73% to 78.19% under different assumptions.

Previous studies also demonstrated that ROTATEQ[®] protects against G8, and the findings from the current study are consistent with the results from these studies. In Africa, vaccine efficacy against G8 was 87.5% (95% CI: 6.8–99.7). In China, Yi et al. reported ROTATEQ[®] VE of 74.1% (95% CI: 33.7–89.8) against G8-related RVGE of any severity and 89.9% (95% CI: 24.3–98.6) against severe G8-related RVGE in Guangdong. Ma et al. estimated ROTATEQ[®] VE against all RVGE at 97% (95% CI: 83–100) in children aged 14 weeks to 2 years and 85.0% (95% CI: 50.0–95.0) against all RVGE of any-severity for all ages, with 79% of cases infected by G8P[8] in Shanghai. Tian et al. reported a VE of 90.4% (95% CI: 28.8–98.7) against all RVGE, with G8 accounting for 61.9% of cases in 2022.

Broad protection across RV types

ROTATEQ[®]'s broad protection is consistent with immunologic evidence indicating that its pentavalent, three-dose formulation induces significant and long-lasting immune responses. Two meta-analyses showed that protection from ROTATEQ[®] against homotypic (matched the G- and P-types of the vaccine) and partially heterotypic (matched only one of the G- or P-types) types was similar. The assessment of protection in clinical trials and observational studies against specific types can be made only against the types circulating during the study period. The present study demonstrates that ROTATEQ[®] is highly effective against the most prevalent RV types in China across different time periods, highlighting its potential to address critical medical needs both worldwide and regionally.

Strength of data source and the study design

The database used in this study provided relevant and reliable real-world data for both primary and secondary objectives.

This study used data previously collected for an MSD-sponsored, large, multicenter post-marketing study that was conducted over four RV peak seasons at 37 sites in 15 provinces across eastern, central, and western China, enrolling 7510 patients. The data was relevant and reliable for the study objectives. A central laboratory and WHO-recommended testing procedures were used, consistent with RV surveillance practices in China, the United States, and Europe. Vaccination history was collected from vaccination cards (checked and photographed/copied) prior to rotavirus testing to avoid outcome-related biases.

A test-negative case-control design was used, offering a robust and efficient approach to evaluate vaccine effectiveness in real-world settings by minimizing bias related to healthcare-seeking behaviors.

Conclusion

- ROTATEQ[®] provides high protection against RVGE regardless of type among children.
- ROTATEQ[®] provides high type-specific protection across different RV G-types, P-types and G/P combinations, including G8, among children.

Marketing Authorisation Holder(s)

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., 126 East Lincoln Ave., P.O. Box 2000, Rahway, New Jersey 07065, USA

Names and affiliations of principal investigators

Principal investigator: PPD

Affiliation: Beijing Children's Hospital, Capital Medical University

2 LIST OF ABBREVIATIONS

AGE	Acute gastroenteritis
CI	Confidence interval
ELISA	Enzyme-linked immunosorbent assay
EU PAS	European Union Post-Authorisation Studies Register
HRV	Hexavalent reassortant rotavirus vaccine
IQR	Interquartile range
IV	Intravenous
LLR	Lanzhou Lamb Rotavirus Vaccine
LLR3	Trivalent Live Reassortant Rotavirus Vaccine
max	Maximum
min	Minimum
MSD	Merck Sharp & Dohme
N	Number of participants
NA	Not Applicable
NE	Not Estimable
NIRDRC	Non-Interventional Research Document Review Committee
nmiss	Number of patients with missing variable information
OR	Odds ratio
RT-PCR	(Reverse transcription) polymerase chain reaction
PRS	Programme Requirements and Specification Document
PSM	Propensity score matching
Q1	25% percentile
Q3	75% percentile
ROTATEQ®	Oral, Live Pentavalent (G1, G2, G3, G4, and P1A[8]) Human–Bovine (WC3) Reassortant Rotavirus Vaccine
RV	Rotavirus
RVGE	Rotavirus acute gastroenteritis
SD	Standard deviation
SQI	Significant quality issue
TND	Test-negative case-control design
VE	Vaccine effectiveness
WC3	Wistar Calf 3 (bovine rotavirus strain)
WHO	World Health Organization

3 INVESTIGATORS

Principal investigator	PPD Beijing Children's Hospital
Sponsor contacts	PPD
Other contacts	PPD, Study manager
Vendor/Collaborator	PPD

4 OTHER RESPONSIBLE PARTIES

Not applicable.

5 MILESTONES

<i>Milestone</i>	<i>Planned date</i>	<i>Actual date</i>
Start of data collection	Q4 2020	October 3, 2020
End of data collection	Q2 2025	April 21, 2025
Registration in the EU PAS register	Q3 2025	Sep 23, 2025
Final report of study results	Q1 2026	April 28, 2026

Note: The data collection dates referenced correspond to the V260-077 study, which serves as the source database for this study.

6 RATIONALE AND BACKGROUND

RV is the leading cause of severe diarrhea in infants and young children in China and worldwide. RV infection was responsible for an estimated 128,500 deaths and 258 million episodes of diarrhea worldwide among children younger than 5 years of age in 2016 [Ref. 5.4: 05BDKP]. In 2009, the World Health Organization recommended RV vaccination for all children worldwide, especially in countries with high numbers of diarrhea-associated deaths [Ref. 5.4: 08NMP5]. In China, RV caused over 40% of diarrhea hospitalizations and about 30% of diarrhea-related outpatient visits in children aged <5 years [Ref. 5.4: 047QHG]. Over 50% of RV-related hospitalizations in China occurred by age 1 year and about 90% occurred by age 2 years [Ref. 5.4: 08NQMT], indicating that a vaccination program with doses given early in infancy has the potential to prevent the majority of the burden of severe RV disease in China [Ref. 5.4: 08NQMT]. The peak seasonality of RV activity in China is typically from October to April of the following year, although this may vary regionally to include additional months.

There are 4 RV vaccines currently approved for marketing in China: ROTATEQ® (Merck & Co., Inc., Rahway, NJ, USA, approved in China on April 12, 2018), Lanzhou Lamb Rotavirus (LLR, Lanzhou Institute of Biological Products, used in China since 2000) vaccine, a trivalent live reassortant RV vaccine (LLR3, Lanzhou Institute of Biological

Products, approved in China on April 17, 2023), and a hexavalent reassortant rotavirus vaccine (HRV, Wuhan Institute of Biological Products, approved in China on August 22, 2025).

ROTATEQ[®] was approved for marketing in China on 12 April 2018. ROTATEQ[®] is an oral, live pentavalent (G1, G2, G3, G4, and P1A[8]) human–bovine (WC3) reassortant RV vaccine indicated for the prevention of RVGE caused by the types G1, G2, G3, G4, and G9 in infants and children in China [Ref. 5.4: 08NSP2]. In the Phase 3 trial (NCT02062385) conducted in China [Ref. 5.4: 04V9CN], overall efficacy against RVGE of any severity and severe RVGE caused by any type was 69.3% (95% CI: 54.5%, 79.7%) and 78.9% (95% CI: 59.1%, 90.1%), respectively. Type-specific efficacy was demonstrated against G1 (74.4%, 95% CI: 47.8%, 88.6%) and G9 (67.4%, 95% CI: 45.2%, 81.4%). However, limited circulation of G2, G3, and G4 during the trial period resulted in insufficient cases to assess efficacy against these types. At the time of marketing authorization in China, the Center for Drug Evaluation (CDE) required establishment of a follow-up database to continuously monitor ROTATEQ[®] effectiveness against RVGE caused by G2, G3, and G4 types in a broader population.

To fulfil this post-marketing requirement, the post-licensure study V260-077 (EU PAS No. EUPAS36666) was conducted across four RV peak seasons (October 2020 to March 2021, October 2021 to April 2022, October 2022 to April 2023, and October 2024 to April 2025) to assess the VE of ROTATEQ[®] against RVGE caused by types G2/G3/G4 and G1/G2/G3/G4/G9 in children in China. V260-077 was a nationwide, multi-season, hospital-based study conducted across more than 35 sites in China. During the study period, RV types other than G1, G2, G3, G4, and G9 were observed among enrolled children, with more than 30% of cases attributed to G8.

Rationale

RV type circulation is dynamic and unpredictable in countries with and without RV vaccination, making the assessment of type-specific VE challenging. From a public health perspective, it is important to assess the VE against all circulating types across different RV peak seasons.

Publications from studies conducted worldwide and in China have demonstrated the effectiveness of ROTATEQ[®] against types other than G1, G2, G3, G4, and G9. However, these studies were either not conducted in Chinese populations or were regional studies within China conducted in a single city or province with limited numbers of specific types, restricting the generalizability of the findings. During V260-077 study period, a substantial proportion of RVGE cases in enrolled children were attributable to other circulating types — notably G8, which accounted for more than 30% of cases — presenting a context to assess ROTATEQ[®] effectiveness against these types.

Therefore, the present study (V260-079) leveraged the V260-077 dataset to retrospectively assess the VE of ROTATEQ[®] against RVGE regardless of type, and to estimate the type-specific VE against individual RV G types, P types, and G/P combinations with sufficient prevalence in the study regions during the study period. No additional sample collection or

laboratory testing was performed; the analysis used existing data from V260-077 study, including documented vaccination history, laboratory-confirmed RV outcomes, and potential covariates. Findings from this study provide additional evidence on the real-world effectiveness of ROTATEQ® in China.

7 RESEARCH QUESTION AND OBJECTIVES

Research objectives:

This is a secondary data analysis using data previously collected for the V260-077 study.

- Primary objective: To assess the effectiveness of ROTATEQ® against RVGE regardless of type in children treated in the hospital for AGE.
- Secondary objective: To assess the type-specific effectiveness of ROTATEQ® against RVGE due to specific RV G types, P types, or G/P combinations in children treated in the hospital for AGE.

8 PROTOCOL AMENDMENTS AND UPDATES

Amendment or Update No.	Date	Section of Study Protocol	Amendment or Update	Reason	NIR DRC Approval Date	NIR DRC Version No.
<1> Original	Dec 4, 2021				Dec 4, 2023	V1.0
<2>	Jan 6, 2025	Template	Amendment: Change the protocol template to PASS SDC template	HA submission potential	April 29, 2025	V2.0
<3>	Jan 6, 2025	List of Abbreviations	Update: The Abbreviation s table is revised to include other abbreviations	Update abbreviations	April 29, 2025	V2.0
<4>	Jan 6, 2025	5 Rationale And Background	Update	Added information on current RV genotype circulation in China based on 2 recently published studies	April 29, 2025	V2.0
<5>	Jan 6, 2025	7.2 Setting: Exclusion Criteria	Update	Added the following exclusion criteria for analysis: 1) Children without collection of vaccination record; 2) Children	April 29, 2025	V2.0

Amendment or Update No.	Date	Section of Study Protocol	Amendment or Update	Reason	NIR DRC Approval Date	NIR DRC Version No.
				vaccinated with mixed RV vaccines		
<6>	Jan 6, 2025	7.3.2 Covariates	Update	Added other covariates collected to keep consistent with V260-077 study	April 29, 2025	V2.0
<7>	Jan 6, 2025	7.4.1 Study Procedures	Update	Added a sentence clarifying ethics committee review at the principal site (approval no. [2020]-Y-007-C-06), use of the electronic data capture system, and the determination that additional ethics committee approval and informed consent were not required	April 29, 2025	V2.0
<8>	Jan 6, 2025	7.5 Sample Size and Power Calculations	Update	Added sentence to update sample size	April 29, 2025	V2.0
<9>	Jun 30, 2025	7.4.1 Study Procedure	Update	The study will require an ethics committee submission	July 7, 2025	V3.0
<10>	Jun 30, 2025	8.1 Informed Consent	Update	The study will require an ethics committee submission	July 7, 2025	V3.0

9 RESEARCH METHODS

9.1 Study Design

The study was conducted using only structured secondary database from the post-licensure study V260-077. No prospective data collection was conducted for this study (V260-079). The analysis applied a test-negative case-control design in which children treated for AGE in hospital settings and with documented RV testing were classified as cases if the RV test was ELISA-positive for the primary objective, the type-specific RVGE (G-type, P-type and G/P Combinations) for the secondary objective, and as controls if the RV test was ELISA-negative. VE was estimated by comparing the odds of ROTATEQ[®] vaccination with 3 doses among cases versus controls.

VE was estimated for (1) RVGE regardless of type (primary objective) and (2) RVGE attributable to specific RV G types, P types, and G/P combinations when sufficient data were available for analysis (secondary objective).

In the V260-077 study, RV testing used ELISA for RV antigen detection, and ELISA-positive specimens underwent reverse transcription–polymerase chain reaction (RT-PCR) for typing. Vaccination history was obtained from vaccination cards or, when vaccination cards were unavailable, from officially authorized immunization registries. Clinical and demographic information was obtained from hospital information systems and/or interviews.

9.2 Setting

The dataset was derived from the V260-077 study population, which comprised children age-eligible to be fully vaccinated with 3 doses of ROTATEQ[®] who received treatment for AGE in hospitals and had documented RV test results.

During V260-077 study enrolment, "Age-eligible" was defined as children who had a minimum age of 16 weeks at the time of AGE onset and a maximum age of 12 weeks (upper age limit for dose 1) when ROTATEQ[®] was launched in the respective hospital catchment area. "Receiving treatment for AGE in hospitals" was defined as admission to an inpatient ward due to AGE, or receipt of intravenous rehydration treatment for at least 2 consecutive calendar days due to AGE in an outpatient hospital setting. "AGE" was defined as 3 or more watery or looser than normal stools within a 24-hour period and/or forceful vomiting, with the onset of gastroenteritis ≤ 14 days prior to admission. No collection of AGE patients was performed in the current study.

Study Duration

The present study is a secondary use of data from V260-077 study that started in October 2020 and covered four RV peak seasons (2020/10–2021/03, 2021/10–2022/04, 2022/10–2023/04, and 2024/10–2025/04).

9.3 Subjects

Children from the V260-077 study dataset with documented RV test results (ELISA positive or negative) were eligible for inclusion in the analysis population.

Children meeting any of the following criteria were excluded from the main statistical analysis population, unless otherwise specified for sensitivity analyses:

- Children without collection of vaccination records
- Children vaccinated with mixed RV vaccines
- Received other RV vaccines than ROTATEQ[®]
- Children with incomplete ROTATEQ[®] schedules or vaccinated out of age-indication
- Children vaccinated with ROTATEQ[®] within 14 days before the onset of AGE

The inclusion and exclusion criteria in this section define the main statistical analysis population used for all primary and secondary study objectives. Exposure group definitions and endpoint definitions are provided in Sections 9.4.1 and 9.4.2.

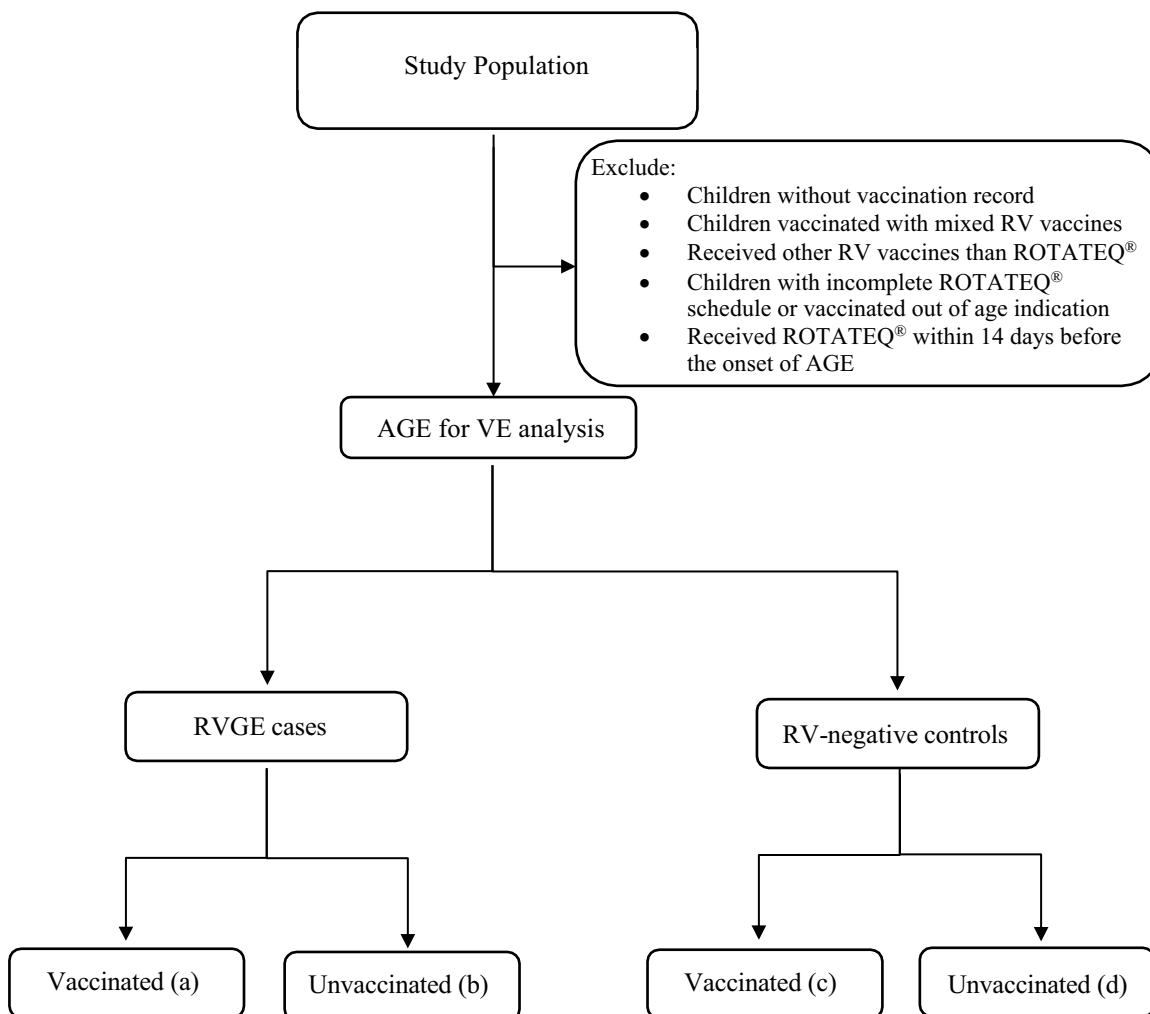


Figure 1. Flow chart to assess the effectiveness of ROTATEQ® against RVGE regardless of type

Note: The flow diagram only applies for the primary objective.

9.4 Variables

9.4.1 Exposure

The exposure of interest was ROTATEQ® vaccination status. Children were considered "vaccinated" if they had received all 3 doses of ROTATEQ® following the recommended schedule at least 14 days before AGE onset. Children were considered "not vaccinated" if they had not received any dose of ROTATEQ® or any other RV vaccines.

9.4.2 Outcome

The outcome of interest was RVGE among children treated for AGE in hospital settings, as determined by RV testing in the structured dataset.

Primary Objective:

- All RVGE cases (ELISA-positive) were defined as cases.
- All RV-negative AGE cases (ELISA-negative) were defined as controls.

Secondary Objective (type-specific):

- RVGE cases attributable to individual RV G types, P types, and G/P combinations were defined as cases.
- All RV-negative AGE cases (ELISA-negative) were defined as controls.

9.4.3 Covariates

- Child's gender
- Age at onset
- Residence locations
- Symptom onset seasons
- Birth seasons
- Regions of study hospitals
- Clinical setting

Analyses were carried out using the available data. A participant with missing data for one variable was included only in calculations that did not involve that variable. This approach allows analysis with larger sample sizes than when using complete datasets of all variables.

In sensitivity analysis 3 (propensity score matching followed by conditional logistic regression) and sensitivity analysis 5, parents' education level was included as an additional covariate.

9.5 Data Sources and Measurement

General Procedure

This study analyzed anonymized data previously collected for the V260-077 study. No additional informed consent was required, as only anonymized data was used, and no new patient information was collected.

Study (V260-079) has been approved by the Ethics Committee of Beijing Children's Hospital (approval No. [2025]-Y-185-A).

In the V260-077 study, RV vaccination history was abstracted from vaccination cards or, if unavailable, from officially authorized application programs. Clinical manifestations and demographic data were obtained from the hospital information system or through interviews. Stool samples collected per routine practice were sent to a central laboratory for testing: Group A rotavirus antigen was detected by ELISA, for ELISA-positive samples, multiplex RT-PCR assays were conducted for further genotyping of the strains.

In the V260-077 study, all inclusion and exclusion criteria were reviewed by the investigator or qualified designee to ensure that the subject qualified.

9.5.1 Study Procedures

Test-negative case-control analysis

Data collection procedures were performed under the V260-077 study.

For the primary objective, the numbers of vaccinated RVGE (regardless of type) cases (*a*), unvaccinated RVGE (regardless of type) cases (*b*), vaccinated RV (-) AGE cases (*c*), and unvaccinated RV (-) AGE cases (*d*) were summed up based on RV ELISA testing results and ROTATEQ[®] vaccination histories for each eligible AGE case (Figure 1).

For the second objective, the type-specific RVGE (G-type, P-type and G/P Combinations) were considered as cases and RV (-) AGE as controls.

Odds ratios (OR) for ROTATEQ[®] vaccination in cases compared with test-negative controls were estimated. The VE was calculated as $(1-OR) \times 100\%$.

9.6 Bias

Bias was addressed through design, operational, and analytic measures during V260-077 data collection and in the V260-079 analysis.

From a study design perspective, the test-negative study design was expected to reduce confounding bias because cases and controls were drawn from the same source population and had similar symptoms, and therefore were likely to have similar care-seeking behaviors and would also be similar with respect to other characteristics, such as age, comorbidities, or access to health care. By collecting vaccination data prior to knowledge of the test results, bias in ascertainment of vaccination among cases and controls could be avoided in this test-negative study [Ref. 5.4: 08NQN5], [Ref. 5.4: 08NNTQ], [Ref. 5.4: 08NNTS]. The case/control status was determined based on rotavirus testing/genotyping in a central lab which could minimize judgement in selection process of case-patients and controls.

We also took measures to mitigate the bias during study execution. In each center, the case screening process and enrollment departments (outpatient, emergency, inpatient) were chosen to cover the core hospital departments whenever possible. Measures were applied to ensure continuous enrollment of cases to reduce selection bias. To avoid selection bias during enrollment based on RV testing results, the investigators in the sites were blinded to the RV testing results by central laboratory while collecting vaccination information. To avoid recall/misclassification bias related to vaccination history, a copy or photography of the vaccination documentation was collected for validation.

9.7 Study Size

This was a secondary data analysis of data from the V260-077 study population (N=7510).

9.8 Data Transformation

For time conversion, 1 month equals 30.4367 days and 1 year equals 365.24 days. Three age variables were derived from date fields in the source dataset, all rounded to 1 decimal place: age at onset in months, calculated as $(\text{AGE onset date} - \text{birth date} + 1 \text{ day}) / 30.4367$; age at onset in weeks, calculated as $(\text{AGE onset date} - \text{birth date} + 1 \text{ day}) / 7$; and age at the time of signing the informed consent form in months, calculated as $(\text{ICF date} - \text{birth date} + 1 \text{ day}) / 30.4367$.

9.8.1 Data Management

The study complied with Good Pharmacoepidemiology Practice (GPP) and all applicable federal, state, and regional laws, rules, and regulations relating to the conduct of the study.

Data management software and hardware:

Electronic data capture and SAS version 9.4

Description of data preparation and methods for data retrieval and collection:

In the V260-077 study, data was collected through the electronic data capture system. During study execution and data collection, the V260-077 study followed a stand-alone data management plan.

In this study, the structured data were directly retrieved from the study population of V260-077. No additional data management was required for this study. No data management plan and case report form were developed for this study.

All data management activities including data capture, data storage, data cleaning, data security, and system backup processes were undertaken by qualified personnel and followed all procedures detailed in a separate data management plan of V260-077.

9.8.2 Programming Quality

This study incorporated the following quality checks for data analysis and reporting programming:

- Creating programme requirements and specification document (PRS).
- Developing and testing of statistical programmes, which includes ensuring the programmes run successfully and all outputs are reviewed to ensure they meet the criteria included in the PRS. This includes validating that all inputs (metadata or parameter values) are correctly specified in the programmes and are consistent with the PRS.
- Independent review and testing, conducted by a second programmer, to ensure that the input and output of the programmes created by the first programmer meet the documented PRS. This includes the following 2 activities:
 - Review of code to ensure the programme aligns with the PRS

- Execution of code and review of results for all scenarios

And may include the following activity:

- Parallel programming of a small piece of critical code.
- Independent double programming, conducted by the second programmer. After programming is completed, the programmes and results of the second programmer are compared to those of the first programmer to ensure consistency. If discrepancies are found, the programmers will discuss and repeat steps until consistency is achieved.
- Review of outputs/results to ensure accuracy and format of each deliverable.

9.9 Statistical Methods

9.9.1 Main Summary Measures

Demographics and disease characteristics were described for the study and analysis populations (see Section 9.9.2), as well as for the case and control groups (see Section 9.4.2). For continuous variables, the number of patients having variable information (non-missing patients, n), number of patients missing the variable information (missing patients, nmiss), mean, standard deviation (Std), median, 25% quantile (Q1), 75% quantile (Q3), minimum (min), and maximum (max) were presented. Among these, min and max were rounded to the same decimal place as the original data (data in V260-077 CRF); mean, median, Q1, and Q3 were rounded to 1 decimal place more than the original data; Std was rounded to 1 decimal place more than the original data.

OR was retained to 3 decimal places, and regression coefficient and P value were retained to 3 decimal places. All of the above statistics were rounded to no more than 3 decimal places. For categorical variables, the number of patients in each category and the percentage were presented. The percentage was rounded to 1 decimal place. The lower and upper bounds of CIs, if needed, were rounded to 2 decimal places.

9.9.2 Main Statistical Methods

Design and analytic framework

This was a test-negative case-control analysis. Children with AGE who were ELISA-positive for RV were classified as cases, and those ELISA-negative were classified as controls.

The exposure was ROTATEQ[®] vaccination status.

Endpoints and case definitions

- **Primary objective (overall VE):** Cases were all RVGE regardless of type (ELISA-positive AGE). Controls were RV-negative AGE (ELISA-negative).

- **Secondary objective (type-specific VE):** Cases were RVGE attributable to specific RV G types, P types, and G/P combinations (as defined by genotyping among ELISA-positive samples). Controls remained RV-negative AGE (ELISA-negative).

Study Population

The study population is referred to as the study population of the V260-077 study (Children age-eligible to be fully vaccinated with 3 doses of ROTATEQ[®] and receiving treatment for AGE in hospitals) that includes individuals with documented RV test results.

Analysis Population

Children from the V260-077 study dataset with documented RV test results (ELISA positive/negative) were included. Children meeting any of the following criteria were excluded from the analysis population:

- Children without collection of vaccination records
- Children vaccinated with mixed RV vaccines
- Received other RV vaccines than ROTATEQ[®]
- Children with incomplete ROTATEQ[®] schedules or vaccinated out of age-indication
- Children vaccinated with ROTATEQ[®] within 14 days before the onset of AGE

Estimation of crude and adjusted VE

For both the primary objective and the secondary objective, crude and adjusted OR for ROTATEQ[®] vaccination for cases compared to controls were estimated using univariate and multivariate logistic regression.

VE was calculated as $(1 - OR) \times 100\%$, along with 95% CIs for both crude and adjusted estimates.

Adjusted ORs were estimated using unconditional multivariate logistic regression models with case/control status as the dependent variable and ROTATEQ[®] vaccination status as the primary independent variable. Potential confounders were evaluated using univariate logistic regression comparing cases and controls; covariates with $P < 0.1$ in univariate models were included in the corresponding multivariate models.

Covariates evaluated for confounding included child age at onset, gender, residence location, symptom onset season, birth season, study hospital region, and clinical setting; parental education level was incorporated in specified sensitivity analyses and/or when imbalance criteria were met. Type-specific adjusted VE estimates were reported only if regression models achieved convergence using the SAS 9.4 default setting.

Statistical programming was performed using SAS version 9.4.

Subgroup analyses

Subgroup analyses: the unadjusted VE and 95% CI were analyzed in subgroups by age of onset group (≤ 11 months, 12-23 months, 24-35 months, ≥ 36 months), gender, birth seasons, symptom onset seasons, residence locations, clinical setting and regions of study hospitals.

Type-specific adjusted VE estimates were reported only when regression models converged under default software settings to ensure numerical stability and interpretability. This conservative approach prioritized reliability of estimates over completeness and is standard practice in analyses involving sparse strata.

9.9.3 Missing Values

For the primary and secondary objectives, analyses were carried out using the available data. A participant with missing data on one variable was used only in calculations that did not involve that variable. This allowed analysis with larger sample sizes than when using complete datasets on all variables.

9.9.4 Sensitivity Analyses

All sensitivity analyses were performed separately for the primary endpoint (VE against RVGE regardless of type) and for the secondary endpoints (type-specific VE) when the regression models could achieve convergence using the SAS 9.4 default setting. These analyses were conducted to assess the reliability and robustness of the vaccine effectiveness under different population assumptions.

Sensitivity analysis 1

To assess the impact of missing vaccination status on study results, a sensitivity analysis was conducted. The sensitivity analysis of primary endpoint was performed by including the population without confirmed vaccination information.

Considering the rotavirus vaccine was paid out of pocket, it is probably more likely that parents from vaccinated children could provide a document on the vaccination comparing with those from unvaccinated children. Assuming that all children with missing information were unvaccinated is therefore the most realistic situation for the VE estimation.

For the sensitivity analysis 1, please refer to the analysis methods of the primary endpoint.

Sensitivity analysis 2:

Age of onset (in months) and symptom onset seasons are considered important confounders and were directly included in the unconditional multivariate logistic regression model, regardless of their P values in the univariate logistic regression, even if $P \geq 0.1$.

The sensitivity analysis 2 was based on the VE analysis populations and refer to the unconditional univariate logistic regression analysis results of the primary endpoint.

Sensitivity analysis 3

Propensity Score Matching (PSM) will be used, and a 3rd sensitivity analysis was conducted using the matching factors: age of onset (in months), gender, education level of the children's parents (college and above for either parent's education level, yes or no), symptom onset seasons. That is, the 3rd sensitivity analysis was performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, college and above for either parent's education level, symptom onset season). As the educational level of the children's parents was only collected in the 2nd, 3rd and 4th peak seasons, children enrolled in the 1st peak season would be missed as the educational level of their parents was not collected. Therefore, the 3rd sensitivity analysis including educational level of the children's parents as a matching factor would lead to a loss of sample size, but it can ensure that the education level of the children's parents variable is balanced between the case and control group.

For the primary endpoint, a 1:3 PSM was used to allow the utmost of matched pairs, if the number permits. For the secondary endpoint, if the number of controls allows, an up-to-1:3 PSM was used.

Based on the above matched sample, univariate analysis for potential confounders (including birth seasons, residence locations, regions of study hospitals and clinical setting) was performed. Dependent variable is group (case group, control group). The significant factors from the conditional univariate logistic regression was included in the conditional multivariate logistic regression model to obtain OR and 95% CI of OR for comparing the ratio of ROTATEQ[®] vaccination among cases and controls after adjusting the potential confounders with $P < 0.1$.

Rules for inclusion of independent variables in the conditional logistic model regression were the same as unconditional logistic regression model.

The 95% CIs of ORs were calculated using the normal approximation, and the 95% CIs of VEs were calculated.

Sensitivity analysis 4

PSM was used and a 4th sensitivity analysis was conducted using the matching factors: age of onset (in months), gender, symptom onset season. That is, the 4th sensitivity analysis was performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

The description of matching ratio is described in Sensitivity Analysis 3.

Based on the above matched sample, univariate analysis for potential confounders (including birth seasons, residence locations, regions of study hospitals and clinical setting) was performed. The significant factors from the conditional univariate logistic regression were included in the conditional multivariate logistic regression model to obtain OR and 95% CI of

OR for comparing the ratio of ROTATEQ[®] vaccination among cases and controls after adjusting the potential confounders with $P < 0.1$.

Rules for inclusion of independent variables in the conditional logistic model regression were the same as unconditional logistic regression model.

The 95% CIs of ORs were calculated using the normal approximation, and the 95% CIs of VEs were calculated.

Sensitivity analysis 5

The 5th sensitivity analysis to include the educational level of the children's parents (college and above for either parent's education level) in multivariate analysis was conducted if the difference of educational level of the children's parents is significant between the case and control groups. The 5th sensitivity analysis was performed based on the children whose data of educational level of the children's parents and potential confounders described in section 9.4.3 are available.

To mitigate the lack of information, it was not included in the primary analysis, but in this sensitivity analysis.

Univariate analysis for potential confounders described above in section 9.4.3 and educational level of the children's parents was performed. The significant factors from the unconditional univariate logistic regression was included in the unconditional multivariate logistic regression model to obtain OR and 95% CI of OR for comparing the ratio of ROTATEQ[®] vaccination among cases and controls after adjusting the potential confounders with $P < 0.1$.

The 95% CIs of ORs were calculated using the normal approximation, and the 95% CIs of VEs were calculated.

9.9.6 Amendments to the Statistical Analysis Plan

Not applicable.

9.10 Quality Control

By signing the protocol, all parties agreed to follow applicable standard operating procedures and to ensure that all existing and new study personnel were appropriately trained so that the study was conducted and data were generated, documented, and reported in compliance with the protocol, Good Pharmacoeconomics Practice, Good Pharmacovigilance Practices, and all applicable laws, rules, and regulations. All parties-maintained transparency and open communication to effectively manage the study and proactively mitigate any risks. The Sponsor conducted routine or for-cause audits to ensure oversight and conduct of the study were performed in accordance with the protocol and applicable quality standards. If a Significant Quality Issue (SQI) was identified at any time during study conduct, it was escalated to the Sponsor immediately. An SQI was defined as any issue with the potential to

negatively impact, directly or indirectly, the rights, safety, or well-being of patients or study participants and/or the integrity of the study data. In the event an audit or SQI resulted in corrective or preventive actions, all parties were expected to appropriately implement the action plan in a timely manner.

10 RESULTS

The source dataset comprised 7510 children with AGE from the V260-077 study; 5594 met eligibility criteria for the analysis population of V260-079 study (1619 RVGE cases; 3975 RV-negative controls). The crude VE against RVGE regardless of type was 86.65% (95% CI: 83.72%, 89.06%), and the adjusted VE was 82.31% (95% CI: 78.23%, 85.63%). Among RVGE cases, the predominant types were G9 (41.2%), G8 (36.3%), and G3 (14.9%); P[8] accounted for 93.6% of typed cases. Adjusted type-specific VE ranged from 75.64% for G8 to 92.17% for G3. Sensitivity analyses confirmed the robustness of VE estimates, with adjusted VE against RVGE regardless of type ranging from 81.66% to 85.27%. Detailed results are presented in the following subsections.

10.1 Participants

10.1.1 Protection of human subjects

This study did not require participant informed consent. The study only involved secondary data analysis using anonymized data and did not involve collecting additional information from the patients.

This study required participant IRB/EC review.

Investigators should ensure that personal identifiers were removed from any study files that was accessible to non-study personnel in accordance with applicable laws and regulations. Whenever feasible, study files should be coded and stripped of personal identifiers, and code keys should be stored separately from study files.

10.1.2 Study Population

This population is referred to as the study population of the V260-077 study, which includes the entire V260-077 study population (N = 7510).

10.1.3 Analysis Population

From the study population of 7510 children, a total of 5594 children (74.5%) met the prespecified eligibility criteria for inclusion in the V260-079 analysis population.

A total of 1916 children (25.5% of the V260-079 study population) were excluded from the V260-079 analysis population. The largest exclusion category was children who had received RV vaccines other than ROTATEQ[®] (n=1092; 14.5% of source population), followed by children vaccinated with ROTATEQ[®] but with incomplete schedule (n=405; 5.4%), children vaccinated with complete ROTATEQ[®] schedule but not following recommended age

indications and/or dosing intervals (n=271; 3.6%), children without vaccination record (n=138; 1.8%), children who had received ROTATEQ[®] within 14 days before onset of AGE (n=56; 0.7%), and children vaccinated with mixed RV vaccines (n=7; 0.1%). A child may have met multiple exclusion criteria; therefore, the sum of individual category may exceed the total number of excluded children (see Table 14.1.1).

Site-level breakdowns of exclusions are provided in Table 14.1.2.

10.1.4 Detailed Characterization of Children Without Vaccination Record

Among the 138 children categorized as "without vaccination record," further characterization revealed that 120 children (87.0% of this exclusion category) had unknown status for any vaccination information, whereas 18 children (13.0% of this exclusion category) had unknown status for partial vaccination information. These children were excluded from the analysis population due to the inability to ascertain RV vaccination status (see Table 14.1.1).

10.1.5 Final Analysis Population Composition

The final analysis population (N=5594) consisted exclusively of children who were either fully vaccinated with ROTATEQ[®] according to the recommended schedule (3 doses with appropriate intervals and age at vaccination) or who were completely unvaccinated against RV. Among the analysis population, 1582 children (28.3%) were fully vaccinated with ROTATEQ[®] and 4012 children (71.7%) were unvaccinated (see Table 14.2.4). The flow of participants from enrolment through analysis population derivation is depicted in Figure 2.

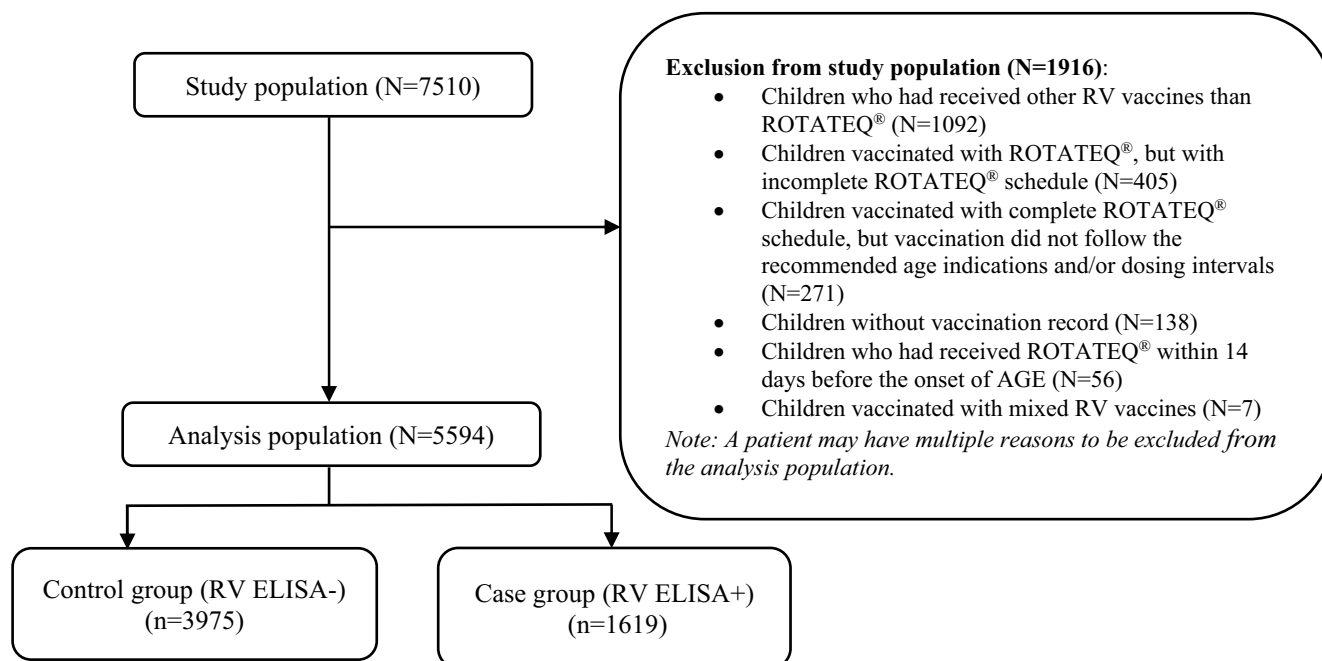


Figure 2. Flow chart of analysis dataset for primary objective

Abbreviations: AGE: acute gastroenteritis; ELISA: enzyme-linked immunosorbent assay; RV: rotavirus.

10.2 Descriptive Data

This section summarizes the demographic and baseline characteristics, disease characteristics, and treatment patterns of children in the analysis population, presented overall and by case/control status.

10.2.1 Demographic Characteristics

The analysis population comprised 5594 children, including 1619 RVGE cases (ELISA-positive) and 3975 RV-negative controls (ELISA-negative). For primary objective, a statistically significant difference was observed in age of onset between cases and controls ($P < 0.001$) in the univariate analysis. The median age of onset was 19.30 months (Interquartile Range [IQR]: 13.80–28.10) in cases and 14.40 months (IQR: 9.50–21.80) in controls, with the largest proportion of illness occurring in the 12–23 month age group in both cases and controls (49.7% in cases and 41.7% in controls). Urban residence was common in both groups but was more frequent among controls than cases (65.6% vs 60.5%; $P < 0.001$), and most children were managed as inpatients (88.9% of cases and 86.0% of controls). Distributions by region of study hospitals and symptom-onset season differed between cases and controls, and parental education data were incomplete, with greater missingness among cases than controls.

As G8 represents one of the highest proportions of all RVGEs in the study, the demographic characteristics of the G8 population are also reported. For G8, statistically significant difference was observed in age of onset between cases and controls ($P < 0.001$) in the univariate analysis. The median age of onset was 20.5 months (IQR: 14.45–29.55) in G8 cases, and 14.4 months (IQR: 9.50–21.80) in controls. Urban residence was common in both groups but was more frequent among controls than cases (65.6% vs 60.4%; $P < 0.001$). More children reside in central China among G8 cases, comparing to the controls (30.1% vs 24.8%; $P < 0.01$). Most children were managed as inpatients (92.5% of cases and 86.0% of controls). More G8 cases were observed in peak season 2021/10–2022/04.

Demographic and clinical characteristics of the case and control groups are summarized in [Table 1](#).

Table 1. Demographic and clinical characteristics of case and control groups in analysis population.

		Cases (all RVGE regardless of type)	Cases (G8)	Controls (RV-)	Total N
Age of Onset in Months (%)	n (nmiss)	1619 (0)	588 (0)	3975 (0)	5594 (0)
	Mean (SD)	23.20 (14.297)***	23.93 (14.061)***	17.88 (12.099)	19.42 (12.998)
	Median	19.30	20.50	14.40	15.70
	Q1, Q3	13.80, 28.10	14.45, 29.55	9.50, 21.80	10.50, 23.70
	Min, Max	3.8, 78.0	3.8, 77.9	3.7, 77.4	3.7, 78.0
	≤11 months	283 (17.5)	98 (16.7)	1481 (37.3)	1764 (31.5)
	12–23 months	804 (49.7)	270 (45.9)	1657 (41.7)	2461 (44.0)

		Cases (all RVGE regardless of type)	Cases (G8)	Controls (RV-)	Total N
	24–35 months	274 (16.9)	120 (20.4)	486 (12.2)	760 (13.6)
	≥36 months	258 (15.9)	100 (17.0)	351 (8.8)	609 (10.9)
Birth Seasons, N (%) ^[1]	RV peak season	947 (58.5)	349 (59.4)	2314 (58.2)	3261 (58.3)
	Non-RV peak season [#]	672 (41.5)	239 (40.6)	1661 (41.8)	2333 (41.7)
Residence Location, N (%)	Urban	980 (60.5)***	355 (60.4)*	2607 (65.6)	3587 (64.1)
	Rural [#]	636 (39.3)	233 (39.6)	1367 (34.4)	2003 (35.8)
	Missing	3 (0.2)	0	1 (0.0)	4 (0.1)
Regions of Study Hospitals, N (%) ^[2]	East [#]	673 (41.6)	270 (45.9)	1980 (49.8)	2653 (47.4)
	Central	392 (24.2)*	177 (30.1)**	985 (24.8)	1377 (24.6)
	West	554 (34.2)***	141 (24.0)	1010 (25.4)	1564 (28.0)
Clinical Settings, N (%)	Inpatients	1439 (88.9)**	544 (92.5)***	3418 (86.0)	4857 (86.8)
	Outpatients [#]	180 (11.1)	44 (7.5)	557 (14.0)	737 (13.2)
Symptom Onset Seasons, N (%) ^[3]	2020/10–2021/03	422 (26.1)***	18 (3.1)	226 (5.7)	648 (11.6)
	2021/10–2022/04	492 (30.4)	339 (57.7)***	1241 (31.2)	1733 (31.0)
	2022/10–2023/04	225 (13.9)***	117 (19.9)	1281 (32.2)	1506 (26.9)
	2024/10–2025/04 [#]	480 (29.6)	114 (19.4)	1227 (30.9)	1707 (30.5)
Gender, N (%)	Male	1001 (61.8)	370 (62.9)	2382 (59.9)	3383 (60.5)
	Female [#]	618 (38.2)	218 (37.1)	1593 (40.1)	2211 (39.5)
College and above for either parent's education level, N (%)	No	425 (26.3)	213 (36.2)	1072 (27.0)	1497 (26.8)
	Yes	760 (46.9)	349 (59.4)	2643 (66.5)	3403 (60.8)
	Missing	434 (26.8)	26 (4.4)	260 (6.5)	694 (12.4)
	Total	1619 (100.0)	588 (100.0)	3975 (100.0)	5594 (100.0)

^[1] RV Peak season: October to April of the following year.

^[2] Regions of Study Hospital: East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong, and Guangdong); Central (Anhui, Henan, Hubei, and Hunan); West (Chongqing, Sichuan, Yunnan, and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 24 and September 30 and met the inclusion criteria were included in the symptom onset season.

[#] Reference level for each independent variable in unconditional univariate logistic regression between the case group and the control group.

*** P < 0.001. ** P < 0.01. * P < 0.05, comparing to controls.

Abbreviations: max: maximum; min: minimum; n: number of participants; nmiss: number of patients with missing variable information; Q1: 25th percentile; Q3: 75th percentile; SD: standard deviation.

10.2.2 Characteristics of AGE Cases at Enrolment

Among the analysis population, the mean age of children at AGE onset was 19.42 months (Std: 12.998). The majority (44.0%) of children with AGE onset were in the age group of 12–23 months. Pre-hospitalization symptom data were available for children in the analysis population. The mean of maximum number of stools per day before visiting the hospital was 6.13 stools per day. The median number of days of diarrhea and vomiting before attending the hospital was 3.0 (IQR 2.0– 4.0) and 2.0 (IQR: 1.0–3.0), respectively. The most frequent diarrhea and vomitus characteristics were watery (63.4%) and gastric contents (95.3%),

respectively. Axillary temperature was measured in 4364 children (78.0% of the analysis population), with a mean of highest reported axillary temperature before hospital visit of 38.35°C among those with measurements. Vomiting prior to hospital presentation was reported in 2988 children (53.4% of the analysis population). Additional detail on vomiting frequency and pre-hospital symptom characteristics is provided in [Table 14.2.2](#).

10.2.3 Treatment of Acute Gastroenteritis

Among children in the analysis population, 4857 (86.8%) were admitted to inpatient wards for treatment of their AGE episode. A total of 5327 (95.2%) children received intravenous fluids with a median of 3.0 (range, 1 to 18) days, and 1655 (29.6%) received oral rehydration with a median of 3.0 (range, 1 to 13) days. Duration distributions for rehydration therapies are provided in [Table 14.2.3](#).

10.3 Outcome Data

10.3.1 Rotavirus Detection by ELISA

RV antigen detection was performed by ELISA on stool specimens in V260-077 study from all children in the analysis population. Based on ELISA results, children were classified as RVGE cases (ELISA-positive) or RV-negative controls (ELISA-negative). Among the analysis population (N=5594), 1619 children (28.9%) tested positive for RV antigen and were classified as RVGE cases, whereas 3975 children (71.1%) tested negative and were classified as RV-negative controls. The RV positivity rate among AGE presentations in the analysis population was 28.9% (see [Table 14.2.5](#)).

10.3.2 Rotavirus Genotyping Results

In V260-077 study, molecular genotyping was performed on RV-positive specimens to characterize circulating G types (VP7 gene) and P types (VP4 gene) using reverse transcription polymerase chain reaction RT-PCR. The detailed frequency of G/P combinations is presented in [Table 2](#).

10.3.2.1 G-Type Distribution Among RVGE Cases

Among 1619 RVGE cases, the predominant G types were G9 (n=667; 41.2%), G8 (n=588; 36.3%), and G3 (n=242; 14.9%). Less common G types included G2 (n=52; 3.2%), G1 (n=17; 1.1%), G4 (n=4; 0.2%), G6 (n=3; 0.2%), G12 (n=1; 0.1%), and G11 (n=1; 0.1%). A total of 44 specimens (2.7%) were G non-typable. The 3 most prevalent G types (G9, G8, and G3) together accounted for 92.4% of all RVGE cases. G8 represented over one-third (36.3%) of all RVGE cases in this analysis population (see [Table 14.2.5](#)).

10.3.2.2 P-Type Distribution Among RVGE Cases

Among RVGE cases with P-type characterization, P[8] was the predominant P type, accounting for 1516 cases (93.6% of typed). Other P types included P[4] (n=63; 3.9%), P[9]

(n=5; 0.3%), and P[6] (n=4; 0.2%). A total of 31 specimens (1.9%) were P non-typable (see [Table 14.2.5](#)).

10.3.2.3 G/P Type Combination Distribution Among RVGE Cases

The most common G/P type combinations among RVGE cases were G9P[8] (n=653; 40.3%), G8P[8] (n=585; 36.1%), and G3P[8] (n=236; 14.6%). Additional combinations of interest included G2P[4] (n=49; 3.0%) and G1P[8] (n=17; 1.1%). The 3 most common G/P combinations—G9P[8], G8P[8], and G3P[8]—collectively represented 91.0% of all RVGE cases. A complete cross-tabulation of G types by P types among RVGE cases is provided in [Table 14.2.6](#).

Table 2. Frequency of Rotavirus A G/P type combinations of analysis population.

Type	P[4] (%)	P[6] (%)	P[8] (%)	P[9] (%)	P non-typable (%)	Total (%)
G1	0	0	17 (1.1)	0	0	17 (1.1)
G2	49 (3.0)	0	2 (0.1)	0	1 (0.1)	52 (3.2)
G3	0	0	236 (14.6)	5 (0.3)	1 (0.1)	242 (14.9)
G4	0	4 (0.2)	0	0	0	4 (0.2)
G6	0	0	1 (0.1)	0	2 (0.1)	3 (0.2)
G8	0	0	585 (36.1)	0	3 (0.2)	588 (36.3)
G9	9 (0.6)	0	653 (40.3)	0	5 (0.3)	667 (41.2)
G11	0	0	1 (0.1)	0	0	1 (0.1)
G12	0	0	1 (0.1)	0	0	1 (0.1)
G non-typable	5 (0.3)	0	20 (1.2)	0	19 (1.2)	44 (2.7)
Total	63 (3.9)	4 (0.2)	1516 (93.6)	5 (0.3)	31 (1.9)	1619 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results.

10.3.3 RV Type Distribution by Stratification Variables

10.3.3.1 RV Type Distribution by Symptom-Onset Season

The distribution of RV G/P genotype combinations varied substantially across symptom-onset seasons captured in the study period. During 2020/10–2021/03 (n=422 ELISA-positive), G9 was dominant (353 cases; 83.6%). During 2021/10–2022/04 (n=492 ELISA-positive), G8 became dominant (339 cases; 68.9%). During 2022/10–2023/04 (n=225 ELISA-positive), G8 remained most common (117 cases; 52.0%) followed by G9 (70 cases; 31.1%). During 2024/10–2025/04 (n=480 ELISA-positive), G3 emerged as the most common type (222 cases; 46.3%), followed by G9 (122 cases; 25.4%) and G8 (114 cases; 23.8%). P[8] remained dominant across all seasons, ranging from 86.7% to 97.5% of typed specimens (see [Table 14.2.7–14.2.10](#)).

10.3.3.2 Type Distribution by Age Group

Genotype distribution was examined across age groups in the analysis population. Among children aged <2 years (n=1087 RVGE cases), G9 was most common (512 cases; 47.1%), followed by G8 (368 cases; 33.9%) and G3 (106 cases; 9.8%). Among children aged ≥2 years (n=532 RVGE cases), G8 was most common (220 cases; 41.4%), followed by G9 (155

cases; 29.1%) and G3 (136 cases; 25.6%). P[8] remained predominant in both age groups (92.9% and 95.1%, respectively) (see [Table 14.2.11](#) and [14.2.15](#)).

10.3.3.3 Type Distribution by Geographic Region

Regional variation in circulating RV genotypes was observed. Among cases from Southern regions (n=1030 RVGE cases), G8 was most common (464 cases; 45.0%), followed by G9 (288 cases; 28.0%) and G3 (189 cases; 18.3%). Among cases from Northern regions (n=589 RVGE cases), G9 was most common (379 cases; 64.3%), followed by G8 (124 cases; 21.1%) and G3 (53 cases; 9.0%). By administrative region, Western China showed the highest proportion of G9 cases (58.7%), whereas Eastern and Central regions had higher proportions of G8 and G3 (see [Table 14.2.12](#), [14.2.16](#), and [14.2.17](#)).

10.3.3.4 Type Distribution by Vaccination Status

Genotype distribution was examined separately among vaccinated and unvaccinated children. Among vaccinated RVGE cases (n=117), G8 was the most common genotype (62 cases; 53.0%), followed by G9 (36 cases; 30.8%) and G3 (11 cases; 9.4%). Among unvaccinated RVGE cases (n=1502), G9 was most common (631 cases; 42.0%), followed by G8 (526 cases; 35.0%) and G3 (231 cases; 15.4%). P[8] was similarly predominant in both groups (93.2% among vaccinated; 93.7% among unvaccinated) (see [Table 14.2.14](#) and [14.2.18](#)).

10.4 Vaccine Effectiveness Results

This section presents the vaccine effectiveness results for the primary objective (VE against RVGE regardless of type) and the secondary objective (type-specific VE against individual G types, P types, and G/P combinations). All VE estimates were calculated as $(1 - OR) \times 100\%$, where the OR compares the odds of full ROTATEQ[®] vaccination among cases versus controls. Adjusted estimates incorporate covariates selected based on univariate associations ($P < 0.1$).

For primary objective, the crude and adjusted VE (95% CI) of ROTATEQ[®] against RVGE regardless of type were 86.65% (83.72%, 89.06%) and 82.31% (78.23%, 85.63%), respectively. Sensitivity analyses yielded adjusted VE estimates ranging from 81.66% to 85.27% across five prespecified assumptions.

For secondary objective, type-specific analyses showed consistent and statistically significant protection across the predominant circulating G types, P types and G/P combinations. The crude and adjusted VE (95% CI) of ROTATEQ[®] against G8 were 79.8% (73.5%, 84.6%) and 75.6% (67.9%, 81.5%), respectively. The adjusted VE point estimates against G8 ranged from 75.73% to 78.19% across the sensitivity analyses evaluated.

10.4.1 Primary Endpoint: Vaccine Effectiveness Against RVGE Regardless of Type

The primary endpoint was VE against RVGE regardless of type, estimated from the full analysis population of 1,619 RVGE cases and 3,975 RV-negative controls. Vaccination status distribution, crude VE, and adjusted VE are presented in the following subsections.

10.4.1.1 Crude Vaccine Effectiveness Against RVGE Regardless of Type

Among the 1619 RVGE cases, 117 (7.2%) were fully vaccinated with ROTATEQ® and 1502 (92.8%) were unvaccinated. Among the 3975 RV-negative controls, 1465 (36.9%) were fully vaccinated and 2510 (63.1%) were unvaccinated.

The crude VE was 86.65% (95% CI: 83.72%, 89.06%); crude VE against all RVGE regardless of type is presented in [Table 3](#) (also see [Table 14.3.1](#)).

Table 3. Crude vaccine effectiveness against all RVGE regardless of type (Primary Objective Analysis).

	Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (95% CI)
Vaccinated	117 (7.2)	1465 (36.9)	1582 (28.3)	86.65% (83.72%, 89.06%)
Unvaccinated	1502 (92.8)	2510 (63.1)	4012 (71.7)	
Total	1619 (100.0)	3975 (100.0)	5594 (100.0)	

The denominator is the number of patients in each group within the analysis population. Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ® following the recommended schedule; unvaccinated denotes children who did not receive any rotavirus vaccines. VE was calculated as one minus the odds of vaccination among cases compared controls without adjusting for potential confounders.

10.4.1.2 Adjusted Vaccine Effectiveness Against RVGE Regardless of Type

Adjusted VE was estimated using unconditional multivariable logistic regression, controlling prespecified covariates that demonstrated association with case-control status ($P < 0.1$ in univariate analysis). These covariates included age at symptom onset (continuous, months), residence location (urban vs rural), geographic region (Central vs East; West vs East), clinical setting (inpatient vs outpatient), and symptom-onset season. The adjusted VE was 82.31% (95% CI: 78.23%, 85.63%), corresponding to an adjusted OR for vaccination of 0.177 (95% CI: 0.144, 0.218).

These multivariable model results are summarized in [Table 4](#) (also see [Table 14.3.5](#)).

Table 4. Adjusted vaccine effectiveness against all RVGE regardless of type (Primary Objective Analysis).

Factors	Statistic	P Value	OR (95% CI)	VE (95% CI)
Age of onset (in months) (Continuous) ^[1]	0.041	<0.001	1.041 (1.036, 1.047)	
Residence location (Urban vs Rural) ^[1]	-0.181	0.010	0.834 (0.727, 0.958)	
Regions of study hospitals (Central vs East) ^[1]	0.234	0.006	1.264 (1.070, 1.491)	
Regions of study hospitals (West vs East) ^[1]	0.578	<0.001	1.782 (1.523, 2.085)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.668	<0.001	1.949 (1.573, 2.415)	
Symptom onset seasons (2020/10–2021/03 vs 2024/10–2025/04) ^[1]	1.774	<0.001	5.894 (4.731, 7.342)	
Symptom onset seasons (2021/10–2022/04 vs 2024/10–2025/04) ^[1]	0.273	0.001	1.314 (1.112, 1.554)	
Symptom onset seasons (2022/10–2023/04 vs 2024/10–2025/04) ^[1]	-0.590	<0.001	0.555 (0.458, 0.672)	
Received ROTATEQ [®] vaccination (fixed variable, Yes vs No) ^[2]	-1.732	<0.001	0.177 (0.144, 0.218)	82.31% (78.23%, 85.63%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Potential confounders that were significantly different ($P < 0.10$) between case and controls group were included in the model.

^[2] “Received ROTATEQ[®] vaccination” was the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for “Received ROTATEQ[®] vaccination”.

10.4.2 Type-Specific Vaccine Effectiveness: G Types (Secondary Objective)

Type-specific VE was evaluated for individual G types, P types, and G/P combinations with sufficient case counts for analysis. Adjusted VE was estimated using unconditional multivariable logistic regression with covariates selected based on univariate associations ($P < 0.10$) within each genotype-specific analysis population. Crude and adjusted estimates for all evaluable types and combinations are summarized in Table 5. G-type-specific results are presented in this section; P-type and G/P combination results are presented in Sections 10.4.4 and 10.4.5, respectively. Detailed descriptive results are provided in [Table 14.4.1.1](#) to [14.4.1.14](#) (crude VE) and [Table 14.4.5.1](#) (Adjusted VE).

Table 5. Crude and adjusted type-specific VE against RVGE (Secondary Objective Analyses).

Types	Case Number (Vaccinated/Unvaccinated) ^[1]	Crude VE (%; 95% CI)	Adjusted VE (%; 95% CI) ^{[2] [3]}
G1	1/16	89.29 (19.17, 98.58)	88.02 (9.38, 98.42)
G2	2/50	93.15 (71.79, 98.33)	90.35 (59.77, 97.69)
G3	11/231	91.84 (85.01, 95.56)	92.17 (85.44, 95.79)
G4	1/3	42.89 (-449.54, 94.06)	NA
G6	1/2	14.33 (-845.55, 92.24)	NA
G8	62/526	79.80 (73.52, 84.60)	75.64 (67.85, 81.54)
G9	36/631	90.23 (86.24, 93.06)	84.15 (77.15, 89.00)
G11	0/1	NA	NA
G12	0/1	NA	NA
P[4]	4/59	88.38 (67.96, 95.79)	85.86 (60.55, 94.93)
P[6]	1/3	42.89 (-449.54, 94.06)	NA
P[8]	109/1407	86.73 (83.70, 89.19)	82.49 (78.30, 85.87)
P[9]	0/5	NA	NA
G1P[8]	1/16	89.29 (19.17, 98.58)	88.02 (9.38, 98.42)
G2P[4]	2/47	92.71 (69.94, 98.23)	90.44 (60.14, 97.71)
G2P[8]	0/2	NA	NA
G3P[8]	11/225	91.62 (84.60, 95.44)	92.01 (85.13, 95.71)
G3P[9]	0/5	NA	NA
G4P[6]	1/3	42.89 (-449.54, 94.06)	NA
G6P[8]	1/0	NA	NA
G8P[8]	61/524	80.05 (73.80, 84.82)	75.93 (68.18, 81.79)
G9P[4]	1/8	78.58 (-71.40, 97.32)	NA
G9P[8]	34/619	90.59 (86.63, 93.38)	84.62 (77.59, 89.44)
G11P[8]	0/1	NA	NA
G12P[8]	0/1	NA	NA

^[1] Case numbers represent the counts used for crude VE estimation. For type-specific VE calculations, controls included 1465 vaccinated and 2510 unvaccinated subjects.

^[2] Adjusted VE was calculated by unconditional multivariate logistic regression. Potential confounders (age of onset, birth seasons, residence locations, regions of study hospitals, clinical setting, symptom onset seasons, and gender) that were significantly different ($P < 0.10$) between case and controls group were included in the model.

^[3] Unconditional multivariate logistic regression was performed for each RV type with the following sample sizes: G1 (n=3991; 17 cases, 3974 controls), G2 (n=4026; 52 cases, 3974 controls), G3 (n=4214; 240 cases, 3974 controls), G8 (n=4562; 588 cases, 3974 controls), G9 (n=4640; 666 cases, 3974 controls), P[4] (n=4038; 63 cases, 3975 controls), P[8] (n=5487; 1513 cases, 3974 controls), G2P[4] (n=4024; 49 cases, 3975 controls), G3P[8] (n=4208; 234 cases, 3974 controls), G8P[8] (n=4559; 585 cases, 3974 controls), and G9P[8] (n=4626; 652 cases, 3974 controls).

VE was calculated by one minus the odds ratios for “vaccinated with ROTATEQ®”.

NA indicates 1) no participant in vaccinated or unvaccinated case group when calculating crude VE, or 2) the data were insufficient for model convergence using the SAS version 9.4 default settings when calculating adjusted VE.

10.4.2.1 Vaccine Effectiveness Against G1 RVGE

The crude VE was 89.29% (95% CI: 19.17%, 98.58%). After adjusting for Residence location (Urban vs Rural) and Gender (Male vs Female), the adjusted VE was 88.02% (95% CI: 9.38%, 98.42%).

10.4.2.2 Vaccine Effectiveness Against G2 RVGE

The crude VE was 93.15% (95% CI: 71.79%, 98.33%). After adjusting for Birth seasons (RV peak season vs Non-RV peak season), Residence location (Urban vs Rural), Regions of study

hospitals (Central, West and East), Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 90.35% (95% CI: 59.77%, 97.69%).

10.4.2.3 Vaccine Effectiveness Against G3 RVGE

The crude VE was 91.84% (95% CI: 85.01%, 95.56%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East), Clinical Setting (Inpatient vs Outpatient) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 92.17% (95% CI: 85.44%, 95.79%).

10.4.2.4 Vaccine Effectiveness Against G8 RVGE

The crude VE was 79.80% (95% CI: 73.52%, 84.60%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East), Clinical Setting (Inpatient vs Outpatient) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 75.64% (95% CI: 67.85%, 81.54%).

10.4.2.5 Vaccine Effectiveness Against G9 RVGE

The crude VE was 90.23% (95% CI: 86.24%, 93.06%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 84.15% (95% CI: 77.15%, 89.00%).

10.4.2.6 Vaccine Effectiveness Against Other G Types

Adjusted VE estimates were not available for certain rare G types due to insufficient case counts and/or lack of statistical model convergence, including G4 (n=4 cases), G6 (n=3 cases), G11 (n=1 case), and G12 (n=1 case) (see Table 2 for crude estimates and [Table 14.2.5](#) and [Table 14.2.6](#) for RV type circulation).

10.4.3 Type-Specific Vaccine Effectiveness: P Types

Type-specific VE was evaluated for individual P types with sufficient case counts for analysis. Adjusted VE was estimated using unconditional multivariable logistic regression, with covariates selected on the basis of univariate associations ($P < 0.10$) within each genotype-specific analysis population. Detailed results for the P-type-specific analyses are presented in the following sections and in [Table 14.4.1.14](#) (crude VE) and [Table 14.4.5.1](#) (Adjusted VE).

10.4.3.1 Vaccine Effectiveness Against P[4] RVGE

The crude VE was 88.38% (95% CI: 67.96%, 95.79%). After adjusting for Birth seasons (RV peak season vs Non-RV peak season), Regions of study hospitals (Central, West and East), Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 85.86% (95% CI: 60.55%, 94.93%).

10.4.3.2 Vaccine Effectiveness Against P[8] RVGE

The crude VE was 86.73% (95% CI: 83.70%, 89.19%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East), Clinical Setting (Inpatient vs Outpatient) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 82.49% (95% CI: 78.30%, 85.87%).

10.4.4 Type-Specific Vaccine Effectiveness: G/P Combinations

Type-specific VE was also evaluated for the most common G/P combinations with sufficient case counts for analysis. Adjusted VE was estimated using unconditional multivariable logistic regression with covariates selected on the basis of univariate associations ($P < 0.10$) within each type-specific analysis population. Complete adjusted VE results for G/P combination-specific analyses are presented in [Table 14.4.5.1](#), whereas RV type combination frequencies are shown in [Table 2](#) and [Table 14.2.6](#).

10.4.4.1 Vaccine Effectiveness Against G1P[8] RVGE

The crude VE was 89.29% (95% CI: 19.17%, 98.58%). After adjusting for Residence location (Urban vs Rural) and Gender (Male vs Female), the adjusted VE was 88.02% (95% CI: 9.38%, 98.42%).

10.4.4.2 Vaccine Effectiveness Against G2P[4] RVGE

The crude VE was 92.71% (95% CI: 69.94%, 98.23%). After adjusting for Regions of study hospitals (Central, West and East) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 90.44% (95% CI: 60.14%, 97.71%).

10.4.4.3 Vaccine Effectiveness Against G3P[8] RVGE

The crude VE was 91.62% (95% CI: 84.60%, 95.44%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East), Clinical Setting (Inpatient vs Outpatient) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 92.01% (95% CI: 85.13%, 95.71%).

10.4.4.4 Vaccine Effectiveness Against G8P[8] RVGE

The crude VE was 80.05% (95% CI: 73.80%, 84.82%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East), Clinical Setting (Inpatient vs Outpatient) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 75.93% (95% CI: 68.18%, 81.79%).

10.4.4.5 Vaccine Effectiveness Against G9P[8] RVGE

The crude VE was 90.59% (95% CI: 86.63%, 93.38%). After adjusting for Age of onset, Residence location (Urban vs Rural), Regions of study hospitals (Central, West and East) and Symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4 and 2024/10-2025/4), the adjusted VE was 84.62% (95% CI: 77.59%, 89.44%).

10.4.5 Subgroup Crude Vaccine Effectiveness Against RVGE Regardless of Type

Subgroup analyses of VE were performed across key demographic and clinical strata. By age group, VE was 85.19% (95% CI: 76.60%, 90.62%) for children ≤ 11 months, 88.11% (95% CI: 84.19%, 91.05%) for 12–23 months, 84.69% (95% CI: 75.64%, 90.38%) for 24–35 months, and 86.11% (95% CI: 75.48%, 92.13%) for ≥ 36 months. By geographic region, VE was 85.75% (95% CI: 80.91%, 89.37%) for Eastern regions, 91.32% (95% CI: 85.64%, 94.75%) for Central regions, and 84.67% (95% CI: 78.72%, 88.95%) for Western regions. By clinical setting, VE was 87.37% (95% CI: 84.30%, 89.84%) for inpatients and 81.00% (95% CI: 68.83%, 88.41%) for outpatients (see [Table 14.3.2](#)).

10.5 Sensitivity Analyses

10.5.1 Sensitivity Analysis Results for Primary Endpoint

10.5.1.1 Sensitivity Analysis 1

Sensitivity analysis 1 included children with missing vaccination information, assuming they were unvaccinated. This analysis included 5719 children (1646 cases, 4073 controls). The crude VE was 86.38% (95% CI: 83.38%, 88.83%), and the adjusted VE was 85.99% (95% CI: 77.84%, 85.36%) (see [Table 14.5.1 – 14.5.5](#)).

10.5.1.2 Sensitivity Analysis 2

Sensitivity analysis 2 forced age at symptom onset and symptom-onset season into the adjusted model regardless of their univariate significance. The adjusted VE was 82.31% (95% CI: 78.23%, 85.63%;) (see [Table 14.5.6](#)).

10.5.1.3 Sensitivity Analysis 3

Sensitivity analysis 3 used PSM on age of onset, Gender, parental education, and symptom onset season, followed by conditional logistic regression. At 1:1 matching ratio, the adjusted VE was 82.43% (95% CI: 77.11%, 86.52%). At 1:2 matching ratio, the adjusted VE was 81.66% (95% CI: 76.88%, 85.45%). At 1:3 matching ratio, the adjusted VE was 82.19% (95% CI: 77.72%, 85.76%) (see [Table 14.5.8.1–14.5.8.3](#)).

10.5.1.4 Sensitivity Analysis 4

Sensitivity analysis 4 used PSM on age of onset, Gender, and symptom onset seasons (excluding parental education), followed by conditional logistic regression. At 1:1 matching ratio, the adjusted VE was 85.01% (95% CI: 80.78%, 88.32%). At 1:2 matching ratio, the adjusted VE was 85.24% (95% CI: 81.57%, 88.18%). At 1:3 matching ratio, the adjusted VE was 85.27% (95% CI: 81.68%, 88.16%) (see [Table 14.5.10.1–14.5.10.3](#)).

10.5.1.5 Sensitivity Analysis 5

Sensitivity analysis 5 included parental education level as an additional covariate in the unconditional multivariable model. The adjusted VE was 82.11% (95% CI: 77.75%, 85.61%). (see [Table 14.5.11](#) and [Table 14.5.12](#)).

10.5.1.6 Summary of Primary Endpoint Sensitivity Analysis Results

The adjusted VE point estimates against RVGE regardless of type ranged from 81.66% to 85.27% across the sensitivity analysis scenarios evaluated (5 sensitivity analyses with multiple matching ratios for analyses 3 and 4). All point estimates fell within or very close to the 95% CI of the primary analysis (78.23%, 85.63%) ([Table 14.3.5](#)), and all lower bounds of sensitivity analysis CIs exceeded 76% (see [Table 14.5.5](#), [14.5.6](#), [14.5.8.1–14.5.8.3](#), [14.5.10.1–14.5.10.3](#), and [14.5.12](#)).

10.5.2 Sensitivity Analysis Results for G8

The adjusted VE point estimates against G8 ranged from 75.73% to 78.19% across the sensitivity analyses evaluated. Sensitivity analysis 1 yielded an adjusted VE of 75.73% (95% CI: 67.05%, 81.13%) ([Table 14.5.5](#)), whereas PSM approaches (sensitivity analyses 3 and 4) yielded estimates up to 78.19% (95% CI: 70.31%, 83.98%). (see [Table 14.6.2.1 -14.6.2.3](#), [14.6.3.1-14.6.3.3](#), [14.6.4.1-14.6.4.3](#)).

10.5.3 Additional Sensitivity Analysis Findings by RV type

Type-specific sensitivity analyses were conducted for other prevalent genotypes across the matched analysis approaches. For G3, adjusted VE ranged from 89.75% to 96.48% across sensitivity analyses 3 and 4, demonstrating consistent protection. For G9, adjusted VE ranged from 81.74% to 86.67% across these analyses. For G2, adjusted VE ranged from 91.09% to 96.46%. Some rare G/P combinations (e.g., G2P[4]) demonstrated model instability in

certain sensitivity analyses due to sparse data, with convergence issues resulting in extreme coefficient estimates (see [Table 14.6.2.1](#), [14.6.2.2](#), [14.6.2.3](#), [14.6.4.1–14.6.4.3](#), and [14.6.6](#)).

10.5.4 Summary of Sensitivity Analysis Findings

Across all prespecified sensitivity analyses, the primary endpoint (RVGE regardless of genotype) adjusted VE estimates ranged from 81.66% to 85.27%, with all estimates remaining consistent with the primary analysis. All lower confidence bounds exceeded 76%, demonstrating consistent vaccine protection. For the G8 genotype, adjusted VE estimates ranged from 75.73% to 78.19%. The narrow spread of VE estimates across sensitivity analyses supports the robustness of the primary effectiveness findings to alternative analytic approaches.

10.6 Safety Results

10.6.1 Scope of Safety Assessment in V260-079

V260-079 leveraged anonymized structured data from V260-077 and did not conduct primary safety surveillance or generate individual case safety reports; the analysis focused on VE outcomes. The V260-079 study was not designed to conduct primary safety surveillance or to generate new individual case safety reports for submission to regulatory agencies. The analysis focused exclusively on VE outcomes using retrospectively collected data.

10.6.2 Safety Data Availability and Reporting Framework

The source data and report content available for this secondary analysis did not include adverse event result summaries or safety signal assessments. Any safety observations arising from the V260-077 surveillance study followed the procedures and reporting mechanisms established in that study protocol, including reporting of serious adverse events within required timeframes.

10.6.3 Safety Conclusion

No adverse event results are presented in this section based on the available V260-079 analysis content. Safety reporting is governed by the pharmacovigilance procedures established for the parent V260-077 study.

11 DISCUSSION

11.1 Key Results

After adjustment for age at onset, residence (urban vs rural), region of study hospitals (Central, West, and East), clinical setting (inpatient vs outpatient), and season of symptom onset, ROTATEQ[®] vaccination reduced the risk of RVGE regardless of type by over 80% (adjusted VE 82.31%; 95% CI: 78.23%, 85.63%). The consistency between crude VE (86.65%) and adjusted VE (82.31%) estimates indicates that the observed protection was not

substantially altered by measured confounders. Sensitivity analyses further confirmed the reliability of these estimates, with adjusted VE ranging from 81.66% to 85.27% across five prespecified analytic approaches that tested alternative assumptions regarding missing vaccination data, forced confounder inclusion, propensity score matching, and adjustment for parental education.

VE findings for ROTATEQ[®] against any RVGE regardless of type were consistent with clinical trial and real-world evidence in the Chinese population. The Phase 3 randomized, double-blind, placebo-controlled trial (NCT02062385) in healthy Chinese infants reported ROTATEQ[®] efficacy of 69.3% (95% CI: 54.5%, 79.7%) against RVGE of any severity and 78.9% (95% CI: 59.1%, 90.1%) against severe RVGE [Ref. 5.4: 04V9CN]. Real-world studies conducted in China have reported ROTATEQ[®] VE estimates between 64.1% and 97%, with most adjusted estimates reaching statistical significance [Ref. 5.4: 08D7WJ], [Ref. 5.4: 094XTL], [Ref. 5.4: 094XSS]. See [Table 6](#) for details.

Table 6. Summary of VE of ROTATEQ[®] against all RVGE regardless of type.

Study Design	Country/Region	RVGE Severity	Adjusted VE against all RVGE	Reference
Clinical trial	China	Any severity	69.3% (95% CI: 54.5%, 79.7%)	Mo, <i>Vaccine</i> , 2017 [Ref. 5.4: 04V9CN]
		Severe	78.9% (95% CI: 59.1%, 90.1%)	
TND	Guangdong, China	Any severity	64.1% (95% CI: 38.0%, 79.2%)	Yi, <i>Infect Dis Ther</i> , 2024 [Ref. 5.4: 094XSS]
		Severe	86.6% (95% CI: 56.8%, 95.9%)	
TND	Shanghai, China	Any Severity	85.0% (95% CI: 50.0%, 95.0%)	Ma, <i>The Journal of Pediatrics</i> , 2023 [Ref. 5.4: 08D7WJ]
		Mild	85.0% (95% CI: 48.0%, 96.0%)	
		Moderate	81.0% (95% CI: -119.0% to 98.0%)	
		14 weeks to 2 years of age	97% (95% CI: 83%, 100%)	
TND	Beijing, China	Not specified (specified as “acute diarrhea”)	90.4% (95% CI: 28.8%, 98.7%)	Tian, <i>Journal of Medical Virology</i> , 2024 [Ref. 5.4: 094XTL]

Abbreviation: TND: test-negative case-control design.

Type-specific analyses showed consistent and statistically significant protection across the predominant circulating G types. Adjusted VE was 92.17% for G3, 90.35% for G2, 88.02% for G1, and 84.15% for G9.

P-type–specific analyses demonstrated adjusted VE of 82.49% for P[8] and 85.86% for P[4].

Subgroup analyses of VE for the primary objective showed consistent protection across age groups (range: 84.69% to 88.11%), regions of study hospitals (84.67% to 91.32%), and clinical settings (81.00% for outpatients, 87.37% for inpatients), indicating that ROTATEQ[®] effectiveness was maintained across the key demographic and clinical strata examined.

11.2 RV circulation and VE against G8

Across four peak seasons (Oct 2020–Mar 2021, Oct 2021–Apr 2022, Oct 2022–Apr 2023, and Oct 2024–Apr 2025) in China, G9 (41.2%), G8 (36.3%), and G3 (14.9%) were the predominant G types, together accounting for more than 92% of typed cases, with G8 alone responsible for 36.3%. The observed prominence of G8 in this dataset is consistent with surveillance data showing increasing G8 prevalence in multiple Chinese provinces in recent years [Ref. 5.4: 094XTL], [Ref. 5.4: 094XY9].

ROTATEQ[®] significantly reduced the risk of G8-attributable RVGE, with an adjusted VE of 75.64% (95% CI: 67.85%, 81.54%). This is the first time that ROTATEQ[®] VE against G8 has been demonstrated in a large, multicenter, observational study in China, with 588 G8 cases providing substantially greater statistical power than any prior assessment. The stability of G8-specific estimates was confirmed across sensitivity analyses, with adjusted VE ranging from 75.73% to 78.19%. These findings are particularly relevant given that G8 is not included in the approved indication of ROTATEQ[®] in China (that includes only efficacy against G1, G2, G3, G4, and G9), demonstrating that ROTATEQ[®] confers meaningful protection beyond its current approved indication.

Previous studies have also demonstrated that ROTATEQ[®] protects against RVGE due to G8. In Africa, a post-hoc analysis of a clinical trial reported VE against severe G8 RVGE of 87.5% (95% CI: 6.8%, 99.7%) based on 9 G8 cases [Ref. 5.4: 08D7X0], [Ref. 5.4: 094XSG], [Ref. 5.4: 08NNTV]. In China, Yi et al. reported ROTATEQ[®] VE of 74.1% (95% CI: 33.7%, 89.8%) against G8 RVGE of any severity and 89.9% (95% CI: 24.3%, 98.6%) against severe G8 RVGE in a regional study in Guangdong province based on 69 G8 cases [Ref. 5.4: 094XSS]. The present study, with 588 G8 cases from 37 sites across 15 provinces, provides more stable and generalizable estimate of ROTATEQ[®] VE against G8 to date. See [Table 7](#) for details.

Table 7. Summary of VE of ROTATEQ[®] against G8 type.

Study Design	Country/Region	Study Size	G8 Cases	RVGE Severity	VE against G8	Reference
TND	Guangdong, China	2650	69	Any severity	74.1% (95% CI: 33.7%, 89.8%)	Yi, <i>Infect Dis Ther</i> , 2024 [Ref. 5.4: 094XSS]
			65	Severe	89.9% (95% CI: 24.3%, 98.6%)	
Clinical trial	Asia and Africa	7679 enrolled	9	Severe	87.5% (95% CI: 6.8%, 99.7%)	Breiman, <i>Vaccine</i> , 2012 [Ref. 5.4: 094XSG]
Clinical trial	Sub-Saharan Africa	5468 enrolled	9	Severe (Vesikari > 11)	1 year of life: 85.8% (95% CI: <0.0%, 99.7%)	Tapia, <i>Vaccine</i> , 2012 [Ref. 5.4: 08NNTV]

Abbreviation: TND: test-negative case-control design.

11.3 Broad Protection

ROTATEQ[®]'s broad protection is consistent with immunologic evidence indicating that its pentavalent, three-dose formulation induces significant and long-lasting immune responses [Ref. 5.4: 094XV5], [Ref. 5.4: 094XTT], [Ref. 5.4: 094XTB]. Two meta-analyses showed that protection from ROTATEQ[®] against homotypic (matched the G- and P-types of the vaccine) and partially heterotypic (matched only one of the G- or P-types) types was similar [Ref. 5.4: 094XSK], [Ref. 5.4: 094Y5G].

The assessment of protection in clinical trials and observational studies against specific types can be made only against the types circulating during the study period. The present study demonstrates that ROTATEQ[®] is highly effective against the most prevalent RV types in China across different time periods, highlighting its potential to address critical medical needs both worldwide and regionally. Despite changes in RV type circulation, the vaccine against RVGE regardless of type remained consistently high, indicating that ROTATEQ[®] effectiveness was maintained across seasons.

11.4 Strengths

This study leveraged the V260-077 database, a large, MSD-sponsored, multicenter post-marketing study conducted across 4 RV peak seasons at 37 hospital sites in 15 provinces spanning Eastern, Central, and Western China, enrolling 7510 children with AGE. The nationwide, multi-season design provides broader geographic and temporal representativeness than prior regional studies conducted in single cities or provinces. The V260-077 study used a central laboratory for RV testing based on ELISA and RT-PCR with WHO-recommended testing procedures. This is consistent with RV surveillance practices in China, the United States, and Europe, thereby ensuring standardized and reliable outcome ascertainment across all study sites [Ref. 5.4: 08D7WR].

The vaccination history was collected prior to rotavirus testing in V260-077, which minimized the potential for outcome-related ascertainment bias in exposure classification. ROTATEQ[®] vaccination status was verified from vaccination cards that were checked and photographed or copied at the time of enrolment, reducing the risk of misclassification due to parental recall.

A test-negative case-control design was used, which is a well-established and efficient approach for evaluating vaccine effectiveness in real-world settings [Ref. 5.4: 08NQN5], [Ref. 5.4: 08NNTQ], [Ref. 5.4: 08NNTS], [Ref. 5.4: 07Z83V], [Ref. 5.4: 08BL02], [Ref. 5.4: 05JNN5], [Ref. 5.4: 08NQNN]. This design minimizes bias due to differential healthcare-seeking behavior, as both cases and controls presented with symptomatic AGE and sought medical care at the same participating hospital facilities, regardless of the underlying etiology. The observed differences between cases and controls in age distribution, seasonality, and geographic region are consistent with known epidemiologic patterns of RV infection and reflect differential disease risk rather than systematic selection bias. Because both groups were drawn from the same source population of children seeking hospital care for AGE, these differences were addressed analytically through covariate adjustment.

The availability of 588 G8 cases provided substantially greater statistical power for G8-specific VE estimation than any prior study, yielding precise estimates with relatively narrow confidence intervals. The inclusion of 5 prespecified sensitivity analyses using diverse analytic approaches (alternative missing data assumptions, forced confounder inclusion, propensity score matching with different matching factor sets, and adjustment for parental education) provided a rigorous assessment of the robustness of the primary findings.

11.5 Limitations

As any observational design, residual confounding cannot be fully excluded. Major covariates — including age at onset, gender, residence location, study hospital region, clinical setting, symptom onset season, and birth season — were prespecified and adjusted for in the multivariable logistic regression models.

Parental educational level was used as a proxy for the socioeconomic situation of the children, which was considered a potential confounder for the severity of AGE and for RV vaccination uptake. This variable was not included in the primary analyses because data were collected only from the 2nd through the 4th peak seasons. To address this limitation, parental education was incorporated into a dedicated sensitivity analysis (Sensitivity Analysis 5). Propensity score matching analyses (Sensitivity Analyses 3 and 4), conducted with and without parental education as a matching factor, yielded similarly high VE estimates, consistent with the primary analysis.

A small proportion of children in the source dataset (138 of 7,510; 1.8%) did not have confirmed vaccination information and were excluded from the primary analysis population. To assess the potential impact of this exclusion, Sensitivity Analysis 1 was conducted assuming that all children with missing vaccination information were unvaccinated.

Type-specific VE estimation is inherently constrained by strain circulation patterns, case counts, and model convergence requirements. For several rare types and G/P combinations, including G4 (n=4), G6 (n=3), G11 (n=1), and G12 (n=1), adjusted VE estimates were not available due to small case numbers.

11.6 Generalizability

The study population was drawn from 37 hospital sites across 15 provinces representing three major geographic regions of China (Eastern, Central, and Western), and data were collected across 4 RV peak seasons spanning from 2020 to 2025. The nationwide, multi-season design enhances the generalizability of the findings to the broader population of Chinese children who present with AGE to hospital settings. Subgroup analyses demonstrated consistent crude VE across age groups, geographic regions, and clinical settings, further supporting the applicability of the results across different demographic and clinical subgroups within the hospital-treated population.

However, the findings are not directly generalizable to milder cases of RVGE managed exclusively in community or primary care settings, as the study population comprised children who sought hospital-level care for AGE. The extent to which ROTATEQ[®] effectiveness against milder, non-hospitalized RVGE may differ from the estimates reported here cannot be determined from this dataset but has generally been shown to be lower. Additionally, depending on the rotavirus circulation, the VE of rotavirus vaccines estimates are specific to the RV types circulating during the study period and in the geographic regions covered by the study sites. RV type circulation varies by region and over time in settings with and without rotavirus vaccination. Therefore, the findings should be interpreted within the context of the circulating RV types during the observation period.

11.7 Public Health Implications

The emergence of G8 as a predominant circulating type in China, accounting for 36.3% of RVGE cases in this study, represented an optimal setting for the assessment of ROTATEQ[®] performance in an evolving epidemiological landscape. The finding that ROTATEQ[®] provides substantial protection against G8 is reassuring from a public health perspective and supports the continued relevance of ROTATEQ[®] vaccination in the context of changing type circulation patterns in China and elsewhere.

The consistency of high VE estimates across geographic regions, age groups, and RV peak seasons observed in this study suggests that the protective effect of ROTATEQ[®] is maintained across the diverse epidemiological and demographic conditions encountered in different parts of China. These findings, together with the evidence of broad type-specific protection, support the continued use of ROTATEQ[®] as part of RV vaccination for the prevention of RVGE in Chinese infants and children.

12 CONCLUSION

- ROTATEQ[®] provides high protection against RVGE regardless of type among children.
- ROTATEQ[®] provides high type-specific protection across different RV G-types, P-types and G/P combinations, including G8.

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14 APPENDICES

Table 14.1.1. Analysis datasets

<i>Items</i>	<i>Total N (%)</i>
V260-079 Study Population	7510 (100.0)
V260-079 Analysis Population	5594 (74.5)
Excluded patients from Analysis Population	1916 (25.5)
Reasons for exclusion from Analysis Population ^[1]	
Children without vaccination record #	138 (1.8)
Children vaccinated with mixed RV vaccines	7 (0.1)
Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	271 (3.6)
Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	405 (5.4)
Children who had received other RV vaccines than ROTATEQ	1092 (14.5)
Children who had received ROTATEQ within 14 days before the onset of AGE	56 (0.7)

The denominator is the number of patients in V260-079 study population.

^[1] A patient may have multiple reasons for exclusion from analysis population.

Including 120 patients unknown for any vaccination information, 18 patients unknown for partial vaccination information.

Table 14.1.2. Analysis datasets for each site (V260-079 study population)

<i>Site Number</i>	<i>Items</i>	<i>Total N (%)</i>
01	V260-079 Study Population	89 (100.0)
	V260-079 Analysis Population	69 (77.5)
	Excluded patients from Analysis Population	20 (22.5)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	2 (2.2)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	1 (1.1)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	4 (4.5)
	Children who had received other RV vaccines than ROTATEQ	13 (14.6)
02	V260-079 Study Population	228 (100.0)
	V260-079 Analysis Population	164 (71.9)
	Excluded patients from Analysis Population	64 (28.1)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	6 (2.6)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	7 (3.1)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	10 (4.4)
	Children who had received other RV vaccines than ROTATEQ	40 (17.5)
	Children who had received ROTATEQ within 14 days before the onset of AGE	3 (1.3)
03	V260-079 Study Population	332 (100.0)
	V260-079 Analysis Population	243 (73.2)
	Excluded patients from Analysis Population	89 (26.8)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	13 (3.9)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	4 (1.2)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	11 (3.3)
	Children who had received other RV vaccines than ROTATEQ	61 (18.4)
04	V260-079 Study Population	107 (100.0)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	V260-079 Analysis Population	77 (72.0)
	Excluded patients from Analysis Population	30 (28.0)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (0.9)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	2 (1.9)
	Children who had received other RV vaccines than ROTATEQ	27 (25.2)
05	V260-079 Study Population	77 (100.0)
	V260-079 Analysis Population	51 (66.2)
	Excluded patients from Analysis Population	26 (33.8)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	10 (13.0)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	5 (6.5)
	Children who had received other RV vaccines than ROTATEQ	11 (14.3)
06	V260-079 Study Population	230 (100.0)
	V260-079 Analysis Population	180 (78.3)
	Excluded patients from Analysis Population	50 (21.7)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (0.4)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	9 (3.9)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	18 (7.8)
	Children who had received other RV vaccines than ROTATEQ	20 (8.7)
	Children who had received ROTATEQ within 14 days before the onset of AGE	5 (2.2)
07	V260-079 Study Population	184 (100.0)
	V260-079 Analysis Population	126 (68.5)
	Excluded patients from Analysis Population	58 (31.5)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (0.5)
	Children vaccinated with mixed RV vaccines	1 (0.5)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	1 (0.5)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	16 (8.7)
	Children who had received other RV vaccines than ROTATEQ	40 (21.7)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.5)
08	V260-079 Study Population	623 (100.0)
	V260-079 Analysis Population	515 (82.7)
	Excluded patients from Analysis Population	108 (17.3)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	8 (1.3)
	Children vaccinated with mixed RV vaccines	1 (0.2)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	13 (2.1)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	25 (4.0)
	Children who had received other RV vaccines than ROTATEQ	63 (10.1)
	Children who had received ROTATEQ within 14 days before the onset of AGE	2 (0.3)
09	V260-079 Study Population	26 (100.0)
	V260-079 Analysis Population	20 (76.9)
	Excluded patients from Analysis Population	6 (23.1)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	1 (3.8)
	Children who had received other RV vaccines than ROTATEQ	5 (19.2)
10	V260-079 Study Population	140 (100.0)
	V260-079 Analysis Population	124 (88.6)
	Excluded patients from Analysis Population	16 (11.4)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	2 (1.4)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	5 (3.6)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	4 (2.9)
	Children who had received other RV vaccines than ROTATEQ	5 (3.6)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.7)
11	V260-079 Study Population	429 (100.0)
	V260-079 Analysis Population	337 (78.6)
	Excluded patients from Analysis Population	92 (21.4)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	2 (0.5)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	11 (2.6)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	16 (3.7)
	Children who had received other RV vaccines than ROTATEQ	63 (14.7)
	Children who had received ROTATEQ within 14 days before the onset of AGE	4 (0.9)
13	V260-079 Study Population	500 (100.0)
	V260-079 Analysis Population	272 (54.4)
	Excluded patients from Analysis Population	228 (45.6)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	10 (2.0)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	40 (8.0)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	30 (6.0)
	Children who had received other RV vaccines than ROTATEQ	148 (29.6)
	Children who had received ROTATEQ within 14 days before the onset of AGE	3 (0.6)
14	V260-079 Study Population	168 (100.0)
	V260-079 Analysis Population	125 (74.4)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Excluded patients from Analysis Population	43 (25.6)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	6 (3.6)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	6 (3.6)
	Children who had received other RV vaccines than ROTATEQ	31 (18.5)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.6)
16	V260-079 Study Population	520 (100.0)
	V260-079 Analysis Population	400 (76.9)
	Excluded patients from Analysis Population	120 (23.1)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	5 (1.0)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	24 (4.6)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	17 (3.3)
	Children who had received other RV vaccines than ROTATEQ	73 (14.0)
	Children who had received ROTATEQ within 14 days before the onset of AGE	2 (0.4)
17	V260-079 Study Population	277 (100.0)
	V260-079 Analysis Population	257 (92.8)
	Excluded patients from Analysis Population	20 (7.2)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	3 (1.1)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	7 (2.5)
	Children who had received other RV vaccines than ROTATEQ	10 (3.6)
18	V260-079 Study Population	162 (100.0)
	V260-079 Analysis Population	118 (72.8)
	Excluded patients from Analysis Population	44 (27.2)
	Reasons for exclusion from Analysis Population ^[1]	

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Children without vaccination record	2 (1.2)
	Children vaccinated with mixed RV vaccines	1 (0.6)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	9 (5.6)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	14 (8.6)
	Children who had received other RV vaccines than ROTATEQ	18 (11.1)
	Children who had received ROTATEQ within 14 days before the onset of AGE	3 (1.9)
19	V260-079 Study Population	29 (100.0)
	V260-079 Analysis Population	26 (89.7)
	Excluded patients from Analysis Population	3 (10.3)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	2 (6.9)
	Children who had received other RV vaccines than ROTATEQ	1 (3.4)
20	V260-079 Study Population	177 (100.0)
	V260-079 Analysis Population	124 (70.1)
	Excluded patients from Analysis Population	53 (29.9)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (0.6)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	3 (1.7)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	11 (6.2)
	Children who had received other RV vaccines than ROTATEQ	32 (18.1)
	Children who had received ROTATEQ within 14 days before the onset of AGE	6 (3.4)
21	V260-079 Study Population	26 (100.0)
	V260-079 Analysis Population	23 (88.5)
	Excluded patients from Analysis Population	3 (11.5)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	1 (3.8)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	2 (7.7)
22	V260-079 Study Population	595 (100.0)
	V260-079 Analysis Population	400 (67.2)
	Excluded patients from Analysis Population	195 (32.8)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	22 (3.7)
	Children vaccinated with mixed RV vaccines	3 (0.5)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	24 (4.0)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	66 (11.1)
	Children who had received other RV vaccines than ROTATEQ	86 (14.5)
	Children who had received ROTATEQ within 14 days before the onset of AGE	9 (1.5)
23	V260-079 Study Population	263 (100.0)
	V260-079 Analysis Population	180 (68.4)
	Excluded patients from Analysis Population	83 (31.6)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	9 (3.4)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	9 (3.4)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	10 (3.8)
	Children who had received other RV vaccines than ROTATEQ	56 (21.3)
24	V260-079 Study Population	277 (100.0)
	V260-079 Analysis Population	198 (71.5)
	Excluded patients from Analysis Population	79 (28.5)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	11 (4.0)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	10 (3.6)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	8 (2.9)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Children who had received other RV vaccines than ROTATEQ	50 (18.1)
25	V260-079 Study Population	667 (100.0)
	V260-079 Analysis Population	541 (81.1)
	Excluded patients from Analysis Population	126 (18.9)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	15 (2.2)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	34 (5.1)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	28 (4.2)
	Children who had received other RV vaccines than ROTATEQ	47 (7.0)
	Children who had received ROTATEQ within 14 days before the onset of AGE	5 (0.7)
26	V260-079 Study Population	7 (100.0)
	V260-079 Analysis Population	5 (71.4)
	Excluded patients from Analysis Population	2 (28.6)
	Reasons for exclusion from Analysis Population ^[1]	
	Children who had received other RV vaccines than ROTATEQ	2 (28.6)
28	V260-079 Study Population	520 (100.0)
	V260-079 Analysis Population	377 (72.5)
	Excluded patients from Analysis Population	143 (27.5)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	17 (3.3)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	17 (3.3)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	46 (8.8)
	Children who had received other RV vaccines than ROTATEQ	62 (11.9)
	Children who had received ROTATEQ within 14 days before the onset of AGE	7 (1.3)
29	V260-079 Study Population	197 (100.0)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	V260-079 Analysis Population	134 (68.0)
	Excluded patients from Analysis Population	63 (32.0)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (0.5)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	12 (6.1)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	11 (5.6)
	Children who had received other RV vaccines than ROTATEQ	39 (19.8)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.5)
30	V260-079 Study Population	91 (100.0)
	V260-079 Analysis Population	79 (86.8)
	Excluded patients from Analysis Population	12 (13.2)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (1.1)
	Children vaccinated with mixed RV vaccines	1 (1.1)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	4 (4.4)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	4 (4.4)
	Children who had received other RV vaccines than ROTATEQ	4 (4.4)
31	V260-079 Study Population	3 (100.0)
	V260-079 Analysis Population	2 (66.7)
	Excluded patients from Analysis Population	1 (33.3)
	Reasons for exclusion from Analysis Population ^[1]	
	Children who had received other RV vaccines than ROTATEQ	1 (33.3)
33	V260-079 Study Population	136 (100.0)
	V260-079 Analysis Population	101 (74.3)
	Excluded patients from Analysis Population	35 (25.7)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	2 (1.5)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	1 (0.7)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	8 (5.9)
	Children who had received other RV vaccines than ROTATEQ	23 (16.9)
	Children who had received ROTATEQ within 14 days before the onset of AGE	2 (1.5)
34	V260-079 Study Population	14 (100.0)
	V260-079 Analysis Population	8 (57.1)
	Excluded patients from Analysis Population	6 (42.9)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	2 (14.3)
	Children who had received other RV vaccines than ROTATEQ	4 (28.6)
37	V260-079 Study Population	61 (100.0)
	V260-079 Analysis Population	47 (77.0)
	Excluded patients from Analysis Population	14 (23.0)
	Reasons for exclusion from Analysis Population ^[1]	
	Children without vaccination record	1 (1.6)
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	3 (4.9)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	2 (3.3)
	Children who had received other RV vaccines than ROTATEQ	7 (11.5)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (1.6)
38	V260-079 Study Population	59 (100.0)
	V260-079 Analysis Population	45 (76.3)
	Excluded patients from Analysis Population	14 (23.7)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	3 (5.1)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
	Children who had received other RV vaccines than ROTATEQ	11 (18.6)
39	V260-079 Study Population	65 (100.0)
	V260-079 Analysis Population	48 (73.8)
	Excluded patients from Analysis Population	17 (26.2)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	4 (6.2)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	3 (4.6)
	Children who had received other RV vaccines than ROTATEQ	10 (15.4)
40	V260-079 Study Population	108 (100.0)
	V260-079 Analysis Population	81 (75.0)
	Excluded patients from Analysis Population	27 (25.0)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	2 (1.9)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	9 (8.3)
	Children who had received other RV vaccines than ROTATEQ	16 (14.8)
41	V260-079 Study Population	40 (100.0)
	V260-079 Analysis Population	38 (95.0)
	Excluded patients from Analysis Population	2 (5.0)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	1 (2.5)
	Children who had received other RV vaccines than ROTATEQ	1 (2.5)
42	V260-079 Study Population	23 (100.0)
	V260-079 Analysis Population	19 (82.6)
	Excluded patients from Analysis Population	4 (17.4)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.1.2. Analysis datasets for each site (V260-079 study population) (Continued)

Site Number	Items	Total N (%)
43	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	2 (8.7)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	2 (8.7)
	V260-079 Study Population	60 (100.0)
	V260-079 Analysis Population	40 (66.7)
	Excluded patients from Analysis Population	20 (33.3)
	Reasons for exclusion from Analysis Population ^[1]	
	Children vaccinated with complete ROTATEQ schedule, but vaccination did not follow the recommended age indications and/or dosing intervals	3 (5.0)
	Children vaccinated with ROTATEQ, but with incomplete ROTATEQ schedule	5 (8.3)
	Children who had received other RV vaccines than ROTATEQ	12 (20.0)

The denominator is the number of patients in V260-079 study population by site.

^[1] A patient may have multiple reasons for exclusion from analysis population.

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Table 14.2.1. Demographics characteristics

		<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Age at the time of signing ICF (months)	n (nmiss)	7510 (0)	5594 (0)
	Mean (Std)	20.12 (13.495)	19.53 (12.988)
	Median	16.30	15.80
	Q1, Q3	10.80, 25.00	10.70, 23.80
	Min, Max	3.7, 79.8	3.7, 78.0
Gender (n, %)	Male	4550 (60.6)	3383 (60.5)
	Female	2960 (39.4)	2211 (39.5)
	Total	7510 (100.0)	5594 (100.0)
Residence location (n, %)	Urban	4904 (65.3)	3587 (64.1)
	Rural	2600 (34.6)	2003 (35.8)
	Missing	6 (0.1)	4 (0.1)
	Total	7510 (100.0)	5594 (100.0)
Education level of the children's father (n, %)	Illiteracy	12 (0.2)	11 (0.2)
	Primary school	109 (1.5)	88 (1.6)
	Junior school	865 (11.5)	620 (11.1)
	Senior school	1410 (18.8)	1056 (18.9)
	College	3781 (50.3)	2787 (49.8)
	Master	230 (3.1)	164 (2.9)
	Doctor	18 (0.2)	16 (0.3)
	Missing	1085 (14.4)	852 (15.2)
	Total	7510 (100.0)	5594 (100.0)
Education level of the children's mother (n, %)	Illiteracy	12 (0.2)	9 (0.2)
	Primary school	123 (1.6)	100 (1.8)
	Junior school	868 (11.6)	635 (11.4)
	Senior school	1373 (18.3)	1025 (18.3)
	College	4008 (53.4)	2941 (52.6)
	Master	188 (2.5)	135 (2.4)
	Doctor	9 (0.1)	7 (0.1)

The denominator is the number of patients in study population or analysis population, respectively.
 nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

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Table 14.2.1. Demographics characteristics (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
College and above for either parent's education level (n, %)	Missing	929 (12.4)	742 (13.3)
	Total	7510 (100.0)	5594 (100.0)
	No	2003 (26.7)	1497 (26.8)
	Yes	4649 (61.9)	3403 (60.8)
	Missing	858 (11.4)	694 (12.4)
		Total	7510 (100.0)
			5594 (100.0)

The denominator is the number of patients in study population or analysis population, respectively.
 nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

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Table 14.2.2. Characteristic of AGE cases at enrollment

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
Age of onset (in weeks)	n (nmiss)	7510 (0)	5594 (0)
	Mean (Std)	87.01 (58.725)	84.43 (56.515)
	Median	70.60	68.30
	Q1, Q3	46.40, 108.10	45.90, 102.90
	Min, Max	16.0, 346.7	16.1, 339.0
Age of onset (in months)	n (nmiss)	7510 (0)	5594 (0)
	Mean (Std)	20.01 (13.506)	19.42 (12.998)
	Median	16.20	15.70
	Q1, Q3	10.70, 24.90	10.50, 23.70
	Min, Max	3.7, 79.7	3.7, 78.0
Age of onset group (n, %)	<=11 months	2292 (30.5)	1764 (31.5)
	12-23 months	3197 (42.6)	2461 (44.0)
	24-35 months	1111 (14.8)	760 (13.6)
	>=36 months	910 (12.1)	609 (10.9)
	Total	7510 (100.0)	5594 (100.0)
Had diarrhea before visiting the hospital (n, %)	Yes	7510 (100.0)	5594 (100.0)
	Total	7510 (100.0)	5594 (100.0)
Number of days of diarrhea before visiting the hospital	n (nmiss)	7510 (0)	5594 (0)
	Mean (Std)	3.25 (2.264)	3.29 (2.281)
	Median	3.00	3.00
	Q1, Q3	2.00, 4.00	2.00, 4.00
	Min, Max	0.5, 14.0	0.5, 14.0

The denominator is the number of patients in study population or analysis population, respectively.

nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] There may be multiple characteristics of diarrhea.

^[2] There may be multiple characteristics of vomiting.

^[3] Vomiting is defined as having at least one day with vomiting.

^[4] The analysis was based on patients with vomiting events (3967 for study population and 2988 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

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Table 14.2.2. Characteristic of AGE cases at enrollment (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
Maximum number of stools per day before visiting the hospital	n (nmiss)	7510 (0)	5594 (0)
	Mean (Std)	6.06 (3.157)	6.13 (3.141)
	Median	5.00	5.00
	Q1, Q3	4.00, 8.00	4.00, 8.00
	Min, Max	3.0, 30.0	3.0, 30.0
Diarrhea characteristic (n, %)^[1]	Watery	4680 (62.3)	3545 (63.4)
	Bloody	276 (3.7)	195 (3.5)
	Rice washed	15 (0.2)	12 (0.2)
	Others	3421 (45.6)	2503 (44.7)
Had vomiting before visiting the hospital (n, %)^[3]	No	3220 (42.9)	2350 (42.0)
	Yes	3967 (52.8)	2988 (53.4)
	Missing	323 (4.3)	256 (4.6)
	Total	7510 (100.0)	5594 (100.0)
Number of days of vomiting before visiting the hospital^[4]	n (nmiss)	3967 (0)	2988 (0)
	Mean (Std)	2.44 (1.637)	2.47 (1.665)
	Median	2.00	2.00
	Q1, Q3	1.00, 3.00	1.00, 3.00
	Min, Max	0.5, 23.0	0.5, 23.0
Maximum number of vomiting per day before visiting the hospital^[4]	n (nmiss)	3495 (472)	2622 (366)
	Mean (Std)	4.72 (3.424)	4.79 (3.420)
	Median	4.00	4.00

The denominator is the number of patients in study population or analysis population, respectively.
 nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] There may be multiple characteristics of diarrhea.

^[2] There may be multiple characteristics of vomiting.

^[3] Vomiting is defined as having at least one day with vomiting.

^[4] The analysis was based on patients with vomiting events (3967 for study population and 2988 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

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Table 14.2.2. Characteristic of AGE cases at enrolment (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	Q1, Q3	2.00, 6.00	2.00, 6.00
	Min, Max	1.0, 30.0	1.0, 30.0
Vomit characteristic (n, %)^{[2][4]}	Gastric contents	3786 (95.4)	2847 (95.3)
	Water samples	56 (1.4)	43 (1.4)
	Bloody vomit	16 (0.4)	12 (0.4)
	Others	252 (6.4)	189 (6.3)
Axillary temperature has been measured before visiting the hospital (n, %)	No	1642 (21.9)	1230 (22.0)
	Yes	5868 (78.1)	4364 (78.0)
	Total	7510 (100.0)	5594 (100.0)
Highest axillary temperature before visiting the hospital (°C)	n (nmiss)	5862 (6)	4359 (5)
	Mean (Std)	38.31 (1.288)	38.35 (1.280)
	Median	38.50	38.60
	Q1, Q3	37.00, 39.30	37.00, 39.40
	Min, Max	36.0, 42.0	36.0, 42.0
Received oral rehydration before visiting the hospital (n, %)	No	5627 (74.9)	4183 (74.8)
	Yes	1134 (15.1)	837 (15.0)
	Missing	749 (10.0)	574 (10.3)
	Total	7510 (100.0)	5594 (100.0)
Total number of days of oral rehydration before visiting the hospital	n (nmiss)	1134 (0)	837 (0)
	Mean (Std)	1.80 (1.192)	1.82 (1.250)
	Median	1.00	1.00

The denominator is the number of patients in study population or analysis population, respectively.

nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] There may be multiple characteristics of diarrhea.

^[2] There may be multiple characteristics of vomiting.

^[3] Vomiting is defined as having at least one day with vomiting.

^[4] The analysis was based on patients with vomiting events (3967 for study population and 2988 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

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Table 14.2.2. Characteristic of AGE cases at enrolment (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	Q1, Q3	1.00, 2.00	1.00, 2.00
	Min, Max	0.5, 12.0	0.5, 12.0
Received intravenous fluid rehydration before visiting the hospital (n, %)	No	4869 (64.8)	3596 (64.3)
	Yes	2077 (27.7)	1560 (27.9)
	Missing	564 (7.5)	438 (7.8)
	Total	7510 (100.0)	5594 (100.0)
Total number of days of intravenous fluid rehydration before visiting the hospital	n (nmiss)	2077 (0)	1560 (0)
	Mean (Std)	1.79 (1.220)	1.82 (1.275)
	Median	1.00	1.00
	Q1, Q3	1.00, 2.00	1.00, 2.00
	Min, Max	1.0, 9.0	1.0, 9.0

The denominator is the number of patients in study population or analysis population, respectively.
 nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] There may be multiple characteristics of diarrhea.

^[2] There may be multiple characteristics of vomiting.

^[3] Vomiting is defined as having at least one day with vomiting.

^[4] The analysis was based on patients with vomiting events (3967 for study population and 2988 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

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Table 14.2.3. Treatment of AGE

		<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Child admitted to the inpatient ward (n, %)	No	969 (12.9)	737 (13.2)
	Yes	6541 (87.1)	4857 (86.8)
	Total	7510 (100.0)	5594 (100.0)
Child received fluid rehydration treatment (n, %) ^[1]	Intravenous fluids	7162 (95.4)	5327 (95.2)
	Oral rehydration	2270 (30.2)	1655 (29.6)
	Nothing	258 (3.4)	190 (3.4)
Number of days of intravenous fluid required by the doctor for the child treated with intravenous fluids	n (nmiss)	7121 (41)	5292 (35)
	Mean (Std)	3.4 (1.89)	3.4 (1.87)
	Median	3.0	3.0
	Q1, Q3	2.0, 4.0	2.0, 4.0
	Min, Max	1, 21	1, 18
Number of days of oral rehydration required by the doctor for the child treated with oral rehydration	n (nmiss)	2174 (96)	1577 (78)
	Mean (Std)	3.2 (1.90)	3.1 (1.93)
	Median	3.0	3.0
	Q1, Q3	2.0, 4.0	2.0, 4.0
	Min, Max	1, 13	1, 13

The denominator is the number of patients in study population or analysis population, respectively.
 nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.
^[1] A patient may have received both intravenous fluid and oral rehydration.

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Table 14.2.4. Vaccination status

		<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Rotavirus vaccination (All sites)	Fully vaccinated with ROTATEQ ^[1]	1612 (21.5)	1582 (28.3)
	Unvaccinated	4012 (53.4)	4012 (71.7)
	Others ^[2]	1886 (25.1)	0
	Total	7510 (100.0)	5594 (100.0)
Rotavirus vaccination (site 01)	Fully vaccinated with ROTATEQ ^[1]	13 (14.6)	13 (18.8)
	Unvaccinated	56 (62.9)	56 (81.2)
	Others ^[2]	20 (22.5)	0
	Total	89 (100.0)	69 (100.0)
Rotavirus vaccination (site 02)	Fully vaccinated with ROTATEQ ^[1]	39 (17.1)	37 (22.6)
	Unvaccinated	127 (55.7)	127 (77.4)
	Others ^[2]	62 (27.2)	0
	Total	228 (100.0)	164 (100.0)
Rotavirus vaccination (site 03)	Fully vaccinated with ROTATEQ ^[1]	39 (11.7)	39 (16.0)
	Unvaccinated	204 (61.4)	204 (84.0)
	Others ^[2]	89 (26.8)	0
	Total	332 (100.0)	243 (100.0)
Rotavirus vaccination (site 04)	Fully vaccinated with ROTATEQ ^[1]	13 (12.1)	13 (16.9)
	Unvaccinated	64 (59.8)	64 (83.1)
	Others ^[2]	30 (28.0)	0
	Total	107 (100.0)	77 (100.0)
Rotavirus vaccination (site 05)	Fully vaccinated with ROTATEQ ^[1]	13 (16.9)	13 (25.5)
	Unvaccinated	38 (49.4)	38 (74.5)
	Others ^[2]	26 (33.8)	0
	Total	77 (100.0)	51 (100.0)
Rotavirus vaccination (site 06)	Fully vaccinated with ROTATEQ ^[1]	59 (25.7)	57 (31.7)

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.4. Vaccination status (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	Unvaccinated	123 (53.5)	123 (68.3)
	Others ^[2]	48 (20.9)	0
	Total	230 (100.0)	180 (100.0)
Rotavirus vaccination (site 07)	Fully vaccinated with ROTATEQ ^[1]	51 (27.7)	50 (39.7)
	Unvaccinated	76 (41.3)	76 (60.3)
	Others ^[2]	57 (31.0)	0
	Total	184 (100.0)	126 (100.0)
Rotavirus vaccination (site 08)	Fully vaccinated with ROTATEQ ^[1]	81 (13.0)	81 (15.7)
	Unvaccinated	434 (69.7)	434 (84.3)
	Others ^[2]	108 (17.3)	0
	Total	623 (100.0)	515 (100.0)
Rotavirus vaccination (site 09)	Fully vaccinated with ROTATEQ ^[1]	2 (7.7)	2 (10.0)
	Unvaccinated	18 (69.2)	18 (90.0)
	Others ^[2]	6 (23.1)	0
	Total	26 (100.0)	20 (100.0)
Rotavirus vaccination (site 10)	Fully vaccinated with ROTATEQ ^[1]	20 (14.3)	19 (15.3)
	Unvaccinated	105 (75.0)	105 (84.7)
	Others ^[2]	15 (10.7)	0
	Total	140 (100.0)	124 (100.0)
Rotavirus vaccination (site 11)	Fully vaccinated with ROTATEQ ^[1]	93 (21.7)	92 (27.3)
	Unvaccinated	245 (57.1)	245 (72.7)
	Others ^[2]	91 (21.2)	0
	Total	429 (100.0)	337 (100.0)
Rotavirus vaccination (site 13)	Fully vaccinated with ROTATEQ ^[1]	97 (19.4)	96 (35.3)
	Unvaccinated	176 (35.2)	176 (64.7)

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.4. Vaccination status (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	Others ^[2]	227 (45.4)	0
	Total	500 (100.0)	272 (100.0)
Rotavirus vaccination (site 14)	Fully vaccinated with ROTATEQ ^[1]	35 (20.8)	35 (28.0)
	Unvaccinated	90 (53.6)	90 (72.0)
	Others ^[2]	43 (25.6)	0
	Total	168 (100.0)	125 (100.0)
Rotavirus vaccination (site 16)	Fully vaccinated with ROTATEQ ^[1]	118 (22.7)	117 (29.3)
	Unvaccinated	283 (54.4)	283 (70.8)
	Others ^[2]	119 (22.9)	0
	Total	520 (100.0)	400 (100.0)
Rotavirus vaccination (site 17)	Fully vaccinated with ROTATEQ ^[1]	17 (6.1)	17 (6.6)
	Unvaccinated	240 (86.6)	240 (93.4)
	Others ^[2]	20 (7.2)	0
	Total	277 (100.0)	257 (100.0)
Rotavirus vaccination (site 18)	Fully vaccinated with ROTATEQ ^[1]	26 (16.0)	24 (20.3)
	Unvaccinated	94 (58.0)	94 (79.7)
	Others ^[2]	42 (25.9)	0
	Total	162 (100.0)	118 (100.0)
Rotavirus vaccination (site 19)	Fully vaccinated with ROTATEQ ^[1]	3 (10.3)	3 (11.5)
	Unvaccinated	23 (79.3)	23 (88.5)
	Others ^[2]	3 (10.3)	0
	Total	29 (100.0)	26 (100.0)
Rotavirus vaccination (site 20)	Fully vaccinated with ROTATEQ ^[1]	65 (36.7)	59 (47.6)
	Unvaccinated	65 (36.7)	65 (52.4)
	Others ^[2]	47 (26.6)	0

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.4. Vaccination status (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	Total	177 (100.0)	124 (100.0)
Rotavirus vaccination (site 21)	Fully vaccinated with ROTATEQ ^[1]	1 (3.8)	1 (4.3)
	Unvaccinated	22 (84.6)	22 (95.7)
	Others ^[2]	3 (11.5)	0
	Total	26 (100.0)	23 (100.0)
Rotavirus vaccination (site 22)	Fully vaccinated with ROTATEQ ^[1]	160 (26.9)	156 (39.0)
	Unvaccinated	244 (41.0)	244 (61.0)
	Others ^[2]	191 (32.1)	0
	Total	595 (100.0)	400 (100.0)
Rotavirus vaccination (site 23)	Fully vaccinated with ROTATEQ ^[1]	70 (26.6)	70 (38.9)
	Unvaccinated	110 (41.8)	110 (61.1)
	Others ^[2]	83 (31.6)	0
	Total	263 (100.0)	180 (100.0)
Rotavirus vaccination (site 24)	Fully vaccinated with ROTATEQ ^[1]	80 (28.9)	80 (40.4)
	Unvaccinated	118 (42.6)	118 (59.6)
	Others ^[2]	79 (28.5)	0
	Total	277 (100.0)	198 (100.0)
Rotavirus vaccination (site 25)	Fully vaccinated with ROTATEQ ^[1]	237 (35.5)	235 (43.4)
	Unvaccinated	306 (45.9)	306 (56.6)
	Others ^[2]	124 (18.6)	0
	Total	667 (100.0)	541 (100.0)
Rotavirus vaccination (site 26)	Fully vaccinated with ROTATEQ ^[1]	1 (14.3)	1 (20.0)
	Unvaccinated	4 (57.1)	4 (80.0)
	Others ^[2]	2 (28.6)	0
	Total	7 (100.0)	5 (100.0)

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.4. Vaccination status (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
Rotavirus vaccination (site 28)	Fully vaccinated with ROTATEQ ^[1]	83 (16.0)	78 (20.7)
	Unvaccinated	299 (57.5)	299 (79.3)
	Others ^[2]	138 (26.5)	0
	Total	520 (100.0)	377 (100.0)
Rotavirus vaccination (site 29)	Fully vaccinated with ROTATEQ ^[1]	49 (24.9)	49 (36.6)
	Unvaccinated	85 (43.1)	85 (63.4)
	Others ^[2]	63 (32.0)	0
	Total	197 (100.0)	134 (100.0)
Rotavirus vaccination (site 30)	Fully vaccinated with ROTATEQ ^[1]	34 (37.4)	34 (43.0)
	Unvaccinated	45 (49.5)	45 (57.0)
	Others ^[2]	12 (13.2)	0
	Total	91 (100.0)	79 (100.0)
Rotavirus vaccination (site 31)	Fully vaccinated with ROTATEQ ^[1]	0	0
	Unvaccinated	2 (66.7)	2 (100.0)
	Others ^[2]	1 (33.3)	0
	Total	3 (100.0)	2 (100.0)
Rotavirus vaccination (site 33)	Fully vaccinated with ROTATEQ ^[1]	21 (15.4)	20 (19.8)
	Unvaccinated	81 (59.6)	81 (80.2)
	Others ^[2]	34 (25.0)	0
	Total	136 (100.0)	101 (100.0)
Rotavirus vaccination (site 34)	Fully vaccinated with ROTATEQ ^[1]	1 (7.1)	1 (12.5)
	Unvaccinated	7 (50.0)	7 (87.5)
	Others ^[2]	6 (42.9)	0
	Total	14 (100.0)	8 (100.0)

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.4. Vaccination status (*Continued*)

		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
Rotavirus vaccination (site 37)	Fully vaccinated with ROTATEQ ^[1]	16 (26.2)	15 (31.9)
	Unvaccinated	32 (52.5)	32 (68.1)
	Others ^[2]	13 (21.3)	0
	Total	61 (100.0)	47 (100.0)
Rotavirus vaccination (site 38)	Fully vaccinated with ROTATEQ ^[1]	8 (13.6)	8 (17.8)
	Unvaccinated	37 (62.7)	37 (82.2)
	Others ^[2]	14 (23.7)	0
	Total	59 (100.0)	45 (100.0)
Rotavirus vaccination (site 39)	Fully vaccinated with ROTATEQ ^[1]	23 (35.4)	23 (47.9)
	Unvaccinated	25 (38.5)	25 (52.1)
	Others ^[2]	17 (26.2)	0
	Total	65 (100.0)	48 (100.0)
Rotavirus vaccination (site 40)	Fully vaccinated with ROTATEQ ^[1]	6 (5.6)	6 (7.4)
	Unvaccinated	75 (69.4)	75 (92.6)
	Others ^[2]	27 (25.0)	0
	Total	108 (100.0)	81 (100.0)
Rotavirus vaccination (site 41)	Fully vaccinated with ROTATEQ ^[1]	7 (17.5)	7 (18.4)
	Unvaccinated	31 (77.5)	31 (81.6)
	Others ^[2]	2 (5.0)	0
	Total	40 (100.0)	38 (100.0)
Rotavirus vaccination (site 42)	Fully vaccinated with ROTATEQ ^[1]	5 (21.7)	5 (26.3)
	Unvaccinated	14 (60.9)	14 (73.7)
	Others ^[2]	4 (17.4)	0
	Total	23 (100.0)	19 (100.0)
Rotavirus vaccination (site 43)	Fully vaccinated with ROTATEQ ^[1]	26 (43.3)	26 (65.0)

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.4. Vaccination status (*Continued*)

	V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
Unvaccinated	14 (23.3)	14 (35.0)
Others ^[2]	20 (33.3)	0
Total	60 (100.0)	40 (100.0)

The denominator is the number of patients in study population or analysis population by site, respectively.

^[1] Children fully vaccinated with ROTATEQ, and vaccinated according to age-indication.

^[2] Others: Including mixed RV vaccines, other RV vaccines, missing vaccination information or vaccinated not according to schedule.

Table 14.2.5. Rotavirus detection and typing results

<i>Symptom onset seasons</i>			<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Symptom onset seasons: Total	ELISA testing results (n, %) ^[1]	Positive	2007 (26.7)	1619 (28.9)
		Negative	5503 (73.3)	3975 (71.1)
		Total	7510 (100.0)	5594 (100.0)
	VP7(G type) results (n, %) ^[2]	G1	26 (1.3)	17 (1.1)
		G2	63 (3.1)	52 (3.2)
		G3	286 (14.3)	242 (14.9)
		G4	4 (0.2)	4 (0.2)
		G6	4 (0.2)	3 (0.2)
		G8	762 (38.0)	588 (36.3)
		G9	800 (39.9)	667 (41.2)
		G11	1 (0.0)	1 (0.1)
		G12	1 (0.0)	1 (0.1)
		G non-typable	60 (3.0)	44 (2.7)
		Total	2007 (100.0)	1619 (100.0)
Symptom onset seasons: 2020/10-2021/3	ELISA testing results (n, %) ^[3]	Positive	486 (62.0)	422 (65.1)
		Negative	298 (38.0)	226 (34.9)
		Total	784 (100.0)	648 (100.0)
	VP7(G type) results (n, %) ^[4]	G1	0	0
		G2	25 (5.1)	21 (5.0)
		G3	2 (0.4)	1 (0.2)
		G4		
		G6		
		G non-typable		
		Total		
	VP4(P type) results (n, %) ^[2]	P[4]	76 (3.8)	63 (3.9)
		P[6]	5 (0.2)	4 (0.2)
		P[8]	1878 (93.6)	1516 (93.6)
		P[9]	7 (0.3)	5 (0.3)
		P non-typable	41 (2.0)	31 (1.9)
		Total	2007 (100.0)	1619 (100.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population for the respective symptom onset season.

^[4] The denominator is the number of patients with ELISA positive results for the respective symptom onset season.

Table 14.2.5. Rotavirus detection and typing results (*Continued*)

<i>Symptom onset seasons</i>		<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
	G4	0	0
	G6	0	0
	G8	22 (4.5)	18 (4.3)
	G9	399 (82.1)	353 (83.6)
	G11	0	0
	G12	0	0
	G non-typable	38 (7.8)	29 (6.9)
	Total	486 (100.0)	422 (100.0)
	VP4(P type) results (n, %) ^[4]		
	P[4]	27 (5.6)	23 (5.5)
	P[6]	0	0
	P[8]	431 (88.7)	378 (89.6)
	P[9]	0	0
	P non-typable	28 (5.8)	21 (5.0)
	Total	486 (100.0)	422 (100.0)
Symptom onset seasons: 2021/10-2022/4 ELISA testing results (n, %) ^[3]			
	Positive	675 (27.4)	492 (28.4)
	Negative	1789 (72.6)	1241 (71.6)
	Total	2464 (100.0)	1733 (100.0)
VP7(G type) results (n, %) ^[4]			
	G1	8 (1.2)	6 (1.2)
	G2	10 (1.5)	8 (1.6)
	G3	7 (1.0)	6 (1.2)
	G4	1 (0.1)	1 (0.2)
	G6	2 (0.3)	1 (0.2)
	G8	468 (69.3)	339 (68.9)
	G9	165 (24.4)	122 (24.8)
	G11	0	0
	G12	0	0
	G non-typable	14 (2.1)	9 (1.8)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population for the respective symptom onset season.

^[4] The denominator is the number of patients with ELISA positive results for the respective symptom onset season.

Table 14.2.5. Rotavirus detection and typing results (*Continued*)

<i>Symptom onset seasons</i>		<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
	Total	675 (100.0)	492 (100.0)
VP4(P type) results (n, %) ^[4]	P[4]	11 (1.6)	9 (1.8)
	P[6]	2 (0.3)	1 (0.2)
	P[8]	652 (96.6)	475 (96.5)
	P[9]	4 (0.6)	3 (0.6)
	P non-typable	6 (0.9)	4 (0.8)
	Total	675 (100.0)	492 (100.0)
Symptom onset seasons: 2022/10-2023/4 ELISA testing results (n, %) ^[3]	Positive	280 (13.5)	225 (14.9)
	Negative	1791 (86.5)	1281 (85.1)
	Total	2071 (100.0)	1506 (100.0)
VP7(G type) results (n, %) ^[4]	G1	10 (3.6)	5 (2.2)
	G2	19 (6.8)	15 (6.7)
	G3	16 (5.7)	13 (5.8)
	G4	2 (0.7)	2 (0.9)
	G6	1 (0.4)	1 (0.4)
	G8	139 (49.6)	117 (52.0)
	G9	90 (32.1)	70 (31.1)
	G11	0	0
	G12	0	0
	G non-typable	3 (1.1)	2 (0.9)
	Total	280 (100.0)	225 (100.0)
VP4(P type) results (n, %) ^[4]	P[4]	31 (11.1)	25 (11.1)
	P[6]	2 (0.7)	2 (0.9)
	P[8]	244 (87.1)	195 (86.7)
	P[9]	1 (0.4)	1 (0.4)
	P non-typable	2 (0.7)	2 (0.9)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population for the respective symptom onset season.

^[4] The denominator is the number of patients with ELISA positive results for the respective symptom onset season.

Table 14.2.5. Rotavirus detection and typing results (*Continued*)

<i>Symptom onset seasons</i>		<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
	Total	280 (100.0)	225 (100.0)
Symptom onset seasons: 2024/10-2025/4 ELISA testing results (n, %) ^[3]	Positive	566 (25.8)	480 (28.1)
	Negative	1625 (74.2)	1227 (71.9)
	Total	2191 (100.0)	1707 (100.0)
VP7(G type) results (n, %) ^[4]	G1	8 (1.4)	6 (1.3)
	G2	9 (1.6)	8 (1.7)
	G3	261 (46.1)	222 (46.3)
	G4	1 (0.2)	1 (0.2)
	G6	1 (0.2)	1 (0.2)
	G8	133 (23.5)	114 (23.8)
	G9	146 (25.8)	122 (25.4)
	G11	1 (0.2)	1 (0.2)
	G12	1 (0.2)	1 (0.2)
	G non-typable	5 (0.9)	4 (0.8)
	Total	566 (100.0)	480 (100.0)
VP4(P type) results (n, %) ^[4]	P[4]	7 (1.2)	6 (1.3)
	P[6]	1 (0.2)	1 (0.2)
	P[8]	551 (97.3)	468 (97.5)
	P[9]	2 (0.4)	1 (0.2)
	P non-typable	5 (0.9)	4 (0.8)
	Total	566 (100.0)	480 (100.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population for the respective symptom onset season.

^[4] The denominator is the number of patients with ELISA positive results for the respective symptom onset season.

Table 14.2.6. Frequency of Rotavirus A G-P type combinations-Total symptom onset seasons (Analysis Population)

<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
G1	0	0	17 (1.1)	0	0	0	17 (1.1)
G2	49 (3.0)	0	2 (0.1)	0	0	1 (0.1)	52 (3.2)
G3	0	0	236 (14.6)	5 (0.3)	0	1 (0.1)	242 (14.9)
G4	0	4 (0.2)	0	0	0	0	4 (0.2)
G6	0	0	1 (0.1)	0	0	2 (0.1)	3 (0.2)
G8	0	0	585 (36.1)	0	0	3 (0.2)	588 (36.3)
G9	9 (0.6)	0	653 (40.3)	0	0	5 (0.3)	667 (41.2)
G11	0	0	1 (0.1)	0	0	0	1 (0.1)
G12	0	0	1 (0.1)	0	0	0	1 (0.1)
Other G-type	0	0	0	0	0	0	0
G non-typable	5 (0.3)	0	20 (1.2)	0	0	19 (1.2)	44 (2.7)
Total	63 (3.9)	4 (0.2)	1516 (93.6)	5 (0.3)	0	31 (1.9)	1619 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results.
 Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;
 Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

**Table 14.2.7. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2020/10-2021/3
 (Analysis Population)**

<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
G1	0	0	0	0	0	0	0
G2	20 (4.7)	0	0	0	0	1 (0.2)	21 (5.0)
G3	0	0	1 (0.2)	0	0	0	1 (0.2)
G4	0	0	0	0	0	0	0
G6	0	0	0	0	0	0	0
G8	0	0	18 (4.3)	0	0	0	18 (4.3)
G9	0	0	350 (82.9)	0	0	3 (0.7)	353 (83.6)
G11	0	0	0	0	0	0	0
G12	0	0	0	0	0	0	0
Other G-type	0	0	0	0	0	0	0
G non-typable	3 (0.7)	0	9 (2.1)	0	0	17 (4.0)	29 (6.9)
Total	23 (5.5)	0	378 (89.6)	0	0	21 (5.0)	422 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results for the current symptom onset season.

Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;

Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

**Table 14.2.8. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2021/10-2022/4
 (Analysis Population)**

<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
G1	0	0	6 (1.2)	0	0	0	6 (1.2)
G2	8 (1.6)	0	0	0	0	0	8 (1.6)
G3	0	0	3 (0.6)	3 (0.6)	0	0	6 (1.2)
G4	0	1 (0.2)	0	0	0	0	1 (0.2)
G6	0	0	1 (0.2)	0	0	0	1 (0.2)
G8	0	0	337 (68.5)	0	0	2 (0.4)	339 (68.9)
G9	0	0	122 (24.8)	0	0	0	122 (24.8)
G11	0	0	0	0	0	0	0
G12	0	0	0	0	0	0	0
Other G-type	0	0	0	0	0	0	0
G non-typable	1 (0.2)	0	6 (1.2)	0	0	2 (0.4)	9 (1.8)
Total	9 (1.8)	1 (0.2)	475 (96.5)	3 (0.6)	0	4 (0.8)	492 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results for the current symptom onset season.
 Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;
 Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

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**Table 14.2.9. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2022/10-2023/4
 (Analysis Population)**

<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
G1	0	0	5 (2.2)	0	0	0	5 (2.2)
G2	15 (6.7)	0	0	0	0	0	15 (6.7)
G3	0	0	12 (5.3)	1 (0.4)	0	0	13 (5.8)
G4	0	2 (0.9)	0	0	0	0	2 (0.9)
G6	0	0	0	0	0	1 (0.4)	1 (0.4)
G8	0	0	117 (52.0)	0	0	0	117 (52.0)
G9	9 (4.0)	0	60 (26.7)	0	0	1 (0.4)	70 (31.1)
G11	0	0	0	0	0	0	0
G12	0	0	0	0	0	0	0
Other G-type	0	0	0	0	0	0	0
G non-typable	1 (0.4)	0	1 (0.4)	0	0	0	2 (0.9)
Total	25 (11.1)	2 (0.9)	195 (86.7)	1 (0.4)	0	2 (0.9)	225 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results for the current symptom onset season.
 Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;
 Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

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Table 14.2.10. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2024/10-2025/4 (Analysis Population)

<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
G1	0	0	6 (1.3)	0	0	0	6 (1.3)
G2	6 (1.3)	0	2 (0.4)	0	0	0	8 (1.7)
G3	0	0	220 (45.8)	1 (0.2)	0	1 (0.2)	222 (46.3)
G4	0	1 (0.2)	0	0	0	0	1 (0.2)
G6	0	0	0	0	0	1 (0.2)	1 (0.2)
G8	0	0	113 (23.5)	0	0	1 (0.2)	114 (23.8)
G9	0	0	121 (25.2)	0	0	1 (0.2)	122 (25.4)
G11	0	0	1 (0.2)	0	0	0	1 (0.2)
G12	0	0	1 (0.2)	0	0	0	1 (0.2)
Other G-type	0	0	0	0	0	0	0
G non-typable	0	0	4 (0.8)	0	0	0	4 (0.8)
Total	6 (1.3)	1 (0.2)	468 (97.5)	1 (0.2)	0	4 (0.8)	480 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results for the current symptom onset season.
 Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;
 Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

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Table 14.2.11. Rotavirus detection and typing results-By Age (<2 years and >=2 years) (Analysis Population)

Age			V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
Total	ELISA testing results (n, %) ^[1]	Positive	2007 (26.7)	1619 (28.9)
		Negative	5503 (73.3)	3975 (71.1)
		Total	7510 (100.0)	5594 (100.0)
	VP7(G type) results (n, %) ^[2]	G1	26 (1.3)	17 (1.1)
		G2	63 (3.1)	52 (3.2)
		G3	286 (14.3)	242 (14.9)
		G4	4 (0.2)	4 (0.2)
		G6	4 (0.2)	3 (0.2)
		G8	762 (38.0)	588 (36.3)
		G9	800 (39.9)	667 (41.2)
		G11	1 (0.0)	1 (0.1)
		G12	1 (0.0)	1 (0.1)
		G non-typable	60 (3.0)	44 (2.7)
		Total	2007 (100.0)	1619 (100.0)
	VP4(P type) results (n, %) ^[2]	P[4]	76 (3.8)	63 (3.9)
		P[6]	5 (0.2)	4 (0.2)
		P[8]	1878 (93.6)	1516 (93.6)
		P[9]	7 (0.3)	5 (0.3)
		P non-typable	41 (2.0)	31 (1.9)
		Total	2007 (100.0)	1619 (100.0)
<2 years	ELISA testing results (n, %) ^[3]	Positive	1286 (23.4)	1087 (25.7)
		Negative	4203 (76.6)	3138 (74.3)
		Total	5489 (100.0)	4225 (100.0)
	VP7(G type) results (n, %) ^[4]	G1	16 (1.2)	13 (1.2)
		G2	52 (4.0)	45 (4.1)
		G3	113 (8.8)	106 (9.8)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by age groups (<2 years and >=2 years).

^[4] The denominator is the number of patients with ELISA positive results, stratified by age groups (<2 years and >=2 years).

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Table 14.2.11. Rotavirus detection and typing results-By Age (<2 years and >=2 years) (Analysis Population) (Continued)

Age		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	G4	3 (0.2)	3 (0.3)
	G6	4 (0.3)	3 (0.3)
	G8	456 (35.5)	368 (33.9)
	G9	591 (46.0)	512 (47.1)
	G11	1 (0.1)	1 (0.1)
	G12	0	0
	G non-typable	50 (3.9)	36 (3.3)
	Total	1286 (100.0)	1087 (100.0)
	VP4(P type) results (n, %) ^[4]		
	P[4]	56 (4.4)	47 (4.3)
	P[6]	3 (0.2)	3 (0.3)
	P[8]	1192 (92.7)	1010 (92.9)
	P[9]	1 (0.1)	1 (0.1)
	P non-typable	34 (2.6)	26 (2.4)
	Total	1286 (100.0)	1087 (100.0)
	>=2 years		
	ELISA testing results (n, %) ^[3]		
	Positive	721 (35.7)	532 (38.9)
	Negative	1300 (64.3)	837 (61.1)
	Total	2021 (100.0)	1369 (100.0)
	VP7(G type) results (n, %) ^[4]		
	G1	10 (1.4)	4 (0.8)
	G2	11 (1.5)	7 (1.3)
	G3	173 (24.0)	136 (25.6)
	G4	1 (0.1)	1 (0.2)
	G6	0	0
	G8	306 (42.4)	220 (41.4)
	G9	209 (29.0)	155 (29.1)
	G11	0	0
	G12	1 (0.1)	1 (0.2)
	G non-typable	10 (1.4)	8 (1.5)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by age groups (<2 years and >=2 years).

^[4] The denominator is the number of patients with ELISA positive results, stratified by age groups (<2 years and >=2 years).

Table 14.2.11. Rotavirus detection and typing results-By Age (<2 years and >=2 years) (Analysis Population) (Continued)

Age		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	Total	721 (100.0)	532 (100.0)
VP4(P type) results (n, %) ^[4]	P[4]	20 (2.8)	16 (3.0)
	P[6]	2 (0.3)	1 (0.2)
	P[8]	686 (95.1)	506 (95.1)
	P[9]	6 (0.8)	4 (0.8)
	P non-typable	7 (1.0)	5 (0.9)
	Total	721 (100.0)	532 (100.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by age groups (<2 years and >=2 years).

^[4] The denominator is the number of patients with ELISA positive results, stratified by age groups (<2 years and >=2 years).

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Table 14.2.12. Rotavirus detection and typing results-By Regions (South and North) (Analysis Population)

<i>Regions*</i>			<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Total	ELISA testing results (n, %) ^[1]	Positive	2007 (26.7)	1619 (28.9)
		Negative	5503 (73.3)	3975 (71.1)
		Total	7510 (100.0)	5594 (100.0)
	VP7(G type) results (n, %) ^[2]	G1	26 (1.3)	17 (1.1)
		G2	63 (3.1)	52 (3.2)
		G3	286 (14.3)	242 (14.9)
		G4	4 (0.2)	4 (0.2)
		G6	4 (0.2)	3 (0.2)
		G8	762 (38.0)	588 (36.3)
		G9	800 (39.9)	667 (41.2)
		G11	1 (0.0)	1 (0.1)
		G12	1 (0.0)	1 (0.1)
		G non-typable	60 (3.0)	44 (2.7)
		Total	2007 (100.0)	1619 (100.0)
	VP4(P type) results (n, %) ^[2]	P[4]	76 (3.8)	63 (3.9)
		P[6]	5 (0.2)	4 (0.2)
		P[8]	1878 (93.6)	1516 (93.6)
		P[9]	7 (0.3)	5 (0.3)
		P non-typable	41 (2.0)	31 (1.9)
		Total	2007 (100.0)	1619 (100.0)
South	ELISA testing results (n, %) ^[3]	Positive	1338 (22.0)	1030 (23.4)
		Negative	4747 (78.0)	3380 (76.6)
		Total	6085 (100.0)	4410 (100.0)
	VP7(G type) results (n, %) ^[4]	G1	24 (1.8)	15 (1.5)
		G2	38 (2.8)	31 (3.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (South and North).

^[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (South and North).

* South (Anhui, Chongqing, Fujian, Guangdong, Henan (Xinyang), Hubei, Hunan, Jiangsu, Sichuan, Yunnan and Zhejiang); North (Beijing, Hebei, Henan (exclude Xinyang), Shaanxi and Shandong).

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Table 14.2.12. Rotavirus detection and typing results-By Regions (South and North) (Analysis Population) (Continued)

Regions*		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	G3	230 (17.2)	189 (18.3)
	G4	4 (0.3)	4 (0.4)
	G6	4 (0.3)	3 (0.3)
	G8	615 (46.0)	464 (45.0)
	G9	371 (27.7)	288 (28.0)
	G11	1 (0.1)	1 (0.1)
	G12	1 (0.1)	1 (0.1)
	G non-typable	50 (3.7)	34 (3.3)
	Total	1338 (100.0)	1030 (100.0)
	VP4(P type) results (n, %) [4]		
	P[4]	43 (3.2)	36 (3.5)
	P[6]	5 (0.4)	4 (0.4)
	P[8]	1250 (93.4)	962 (93.4)
	P[9]	7 (0.5)	5 (0.5)
	P non-typable	33 (2.5)	23 (2.2)
	Total	1338 (100.0)	1030 (100.0)
	North		
	ELISA testing results (n, %) [3]		
	Positive	669 (46.9)	589 (49.7)
	Negative	756 (53.1)	595 (50.3)
	Total	1425 (100.0)	1184 (100.0)
	VP7(G type) results (n, %) [4]		
	G1	2 (0.3)	2 (0.3)
	G2	25 (3.7)	21 (3.6)
	G3	56 (8.4)	53 (9.0)
	G4	0	0
	G6	0	0
	G8	147 (22.0)	124 (21.1)
	G9	429 (64.1)	379 (64.3)
	G11	0	0

[1] The denominator is the number of patients in study population or analysis population, respectively.

[2] The denominator is the number of patients with ELISA positive results.

[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (South and North).

[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (South and North).

* South (Anhui, Chongqing, Fujian, Guangdong, Henan (Xinyang), Hubei, Hunan, Jiangsu, Sichuan, Yunnan and Zhejiang); North (Beijing, Hebei, Henan (exclude Xinyang), Shaanxi and Shandong).

Table 14.2.12. Rotavirus detection and typing results-By Regions (South and North) (Analysis Population) (Continued)

Regions*		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
VP4(P type) results (n, %) ^[4]	G12	0	0
	G non-typable	10 (1.5)	10 (1.7)
	Total	669 (100.0)	589 (100.0)
	P[4]	33 (4.9)	27 (4.6)
	P[6]	0	0
	P[8]	628 (93.9)	554 (94.1)
	P[9]	0	0
	P non-typable	8 (1.2)	8 (1.4)
	Total	669 (100.0)	589 (100.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (South and North).

^[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (South and North).

* South (Anhui, Chongqing, Fujian, Guangdong, Henan (Xinyang), Hubei, Hunan, Jiangsu, Sichuan, Yunnan and Zhejiang); North (Beijing, Hebei, Henan (exclude Xinyang), Shaanxi and Shandong).

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Table 14.2.13. Rotavirus detection and typing results-By Regions (East, Central and West) (Analysis Population)

<i>Regions*</i>			<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Total	ELISA testing results (n, %) ^[1]	Positive	2007 (26.7)	1619 (28.9)
		Negative	5503 (73.3)	3975 (71.1)
		Total	7510 (100.0)	5594 (100.0)
	VP7(G type) results (n, %) ^[2]	G1	26 (1.3)	17 (1.1)
		G2	63 (3.1)	52 (3.2)
		G3	286 (14.3)	242 (14.9)
		G4	4 (0.2)	4 (0.2)
		G6	4 (0.2)	3 (0.2)
		G8	762 (38.0)	588 (36.3)
		G9	800 (39.9)	667 (41.2)
		G11	1 (0.0)	1 (0.1)
		G12	1 (0.0)	1 (0.1)
		G non-typable	60 (3.0)	44 (2.7)
		Total	2007 (100.0)	1619 (100.0)
	VP4(P type) results (n, %) ^[2]	P[4]	76 (3.8)	63 (3.9)
		P[6]	5 (0.2)	4 (0.2)
		P[8]	1878 (93.6)	1516 (93.6)
		P[9]	7 (0.3)	5 (0.3)
		P non-typable	41 (2.0)	31 (1.9)
		Total	2007 (100.0)	1619 (100.0)
East	ELISA testing results (n, %) ^[3]	Positive	791 (23.6)	673 (25.4)
		Negative	2559 (76.4)	1980 (74.6)
		Total	3350 (100.0)	2653 (100.0)
	VP7(G type) results (n, %) ^[4]	G1	14 (1.8)	9 (1.3)
		G2	9 (1.1)	9 (1.3)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (East, Central and West).

^[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (East, Central and West).

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

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Table 14.2.13. Rotavirus detection and typing results-By Regions (East, Central and West) (Analysis Population)
(Continued)

Regions*		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
	G3	178 (22.5)	151 (22.4)
	G4	0	0
	G6	0	0
	G8	314 (39.7)	270 (40.1)
	G9	240 (30.3)	207 (30.8)
	G11	0	0
	G12	1 (0.1)	1 (0.1)
	G non-typable	35 (4.4)	26 (3.9)
	Total	791 (100.0)	673 (100.0)
	VP4(P type) results (n, %) [4]		
	P[4]	21 (2.7)	19 (2.8)
	P[6]	0	0
	P[8]	742 (93.8)	633 (94.1)
	P[9]	5 (0.6)	3 (0.4)
	P non-typable	23 (2.9)	18 (2.7)
	Total	791 (100.0)	673 (100.0)
	Central		
	ELISA testing results (n, %) [3]		
	Positive	503 (26.0)	392 (28.5)
	Negative	1435 (74.0)	985 (71.5)
	Total	1938 (100.0)	1377 (100.0)
	VP7(G type) results (n, %) [4]		
	G1	6 (1.2)	5 (1.3)
	G2	20 (4.0)	16 (4.1)
	G3	63 (12.5)	52 (13.3)
	G4	1 (0.2)	1 (0.3)
	G6	0	0
	G8	237 (47.1)	177 (45.2)
	G9	168 (33.4)	135 (34.4)
	G11	0	0

[1] The denominator is the number of patients in study population or analysis population, respectively.

[2] The denominator is the number of patients with ELISA positive results.

[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (East, Central and West).

[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (East, Central and West).

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

Table 14.2.13. Rotavirus detection and typing results-By Regions (East, Central and West) (Analysis Population)
(Continued)

Regions*		V260-079 Study Population (N=7510)	V260-079 Analysis Population (N=5594)
West	G12	0	0
	G non-typable	8 (1.6)	6 (1.5)
	Total	503 (100.0)	392 (100.0)
	VP4(P type) results (n, %) [4]		
	P[4]	19 (3.8)	15 (3.8)
	P[6]	2 (0.4)	1 (0.3)
	P[8]	475 (94.4)	370 (94.4)
	P[9]	1 (0.2)	1 (0.3)
	P non-typable	6 (1.2)	5 (1.3)
	Total	503 (100.0)	392 (100.0)
	ELISA testing results (n, %) [3]		
	Positive	713 (32.1)	554 (35.4)
	Negative	1509 (67.9)	1010 (64.6)
	Total	2222 (100.0)	1564 (100.0)
	VP7(G type) results (n, %) [4]		
	G1	6 (0.8)	3 (0.5)
	G2	34 (4.8)	27 (4.9)
	G3	45 (6.3)	39 (7.0)
	G4	3 (0.4)	3 (0.5)
	G6	4 (0.6)	3 (0.5)
	G8	211 (29.6)	141 (25.5)
	G9	392 (55.0)	325 (58.7)
	G11	1 (0.1)	1 (0.2)
	G12	0	0
	G non-typable	17 (2.4)	12 (2.2)
	Total	713 (100.0)	554 (100.0)
	VP4(P type) results (n, %) [4]		
	P[4]	36 (5.0)	29 (5.2)
	P[6]	3 (0.4)	3 (0.5)

[1] The denominator is the number of patients in study population or analysis population, respectively.

[2] The denominator is the number of patients with ELISA positive results.

[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (East, Central and West).

[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (East, Central and West).

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

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Table 14.2.13. Rotavirus detection and typing results-By Regions (East, Central and West) (Analysis Population)
(Continued)

<i>Regions*</i>	<i>V260-079 Study Population (N=7510)</i>	<i>V260-079 Analysis Population (N=5594)</i>
P[8]	661 (92.7)	513 (92.6)
P[9]	1 (0.1)	1 (0.2)
P non-typable	12 (1.7)	8 (1.4)
Total	713 (100.0)	554 (100.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by region groups (East, Central and West).

^[4] The denominator is the number of patients with ELISA positive results, stratified by region groups (East, Central and West).

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

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Table 14.2.14. Rotavirus detection and typing results-By Vaccination status (Vaccinated and Unvaccinated) (Analysis Population)

<i>Vaccination status</i>			<i>V260-079 Study Population (N=5624)</i>	<i>V260-079 Analysis Population (N=5594)</i>
Total	ELISA testing results (n, %) ^[1]	Positive	1620 (28.8)	1619 (28.9)
		Negative	4004 (71.2)	3975 (71.1)
		Total	5624 (100.0)	5594 (100.0)
	VP7(G type) results (n, %) ^[2]	G1	17 (1.0)	17 (1.1)
		G2	52 (3.2)	52 (3.2)
		G3	243 (15.0)	242 (14.9)
		G4	4 (0.2)	4 (0.2)
		G6	3 (0.2)	3 (0.2)
		G8	588 (36.3)	588 (36.3)
		G9	667 (41.2)	667 (41.2)
		G11	1 (0.1)	1 (0.1)
		G12	1 (0.1)	1 (0.1)
		G non-typable	44 (2.7)	44 (2.7)
		Total	1620 (100.0)	1619 (100.0)
	VP4(P type) results (n, %) ^[2]	P[4]	63 (3.9)	63 (3.9)
		P[6]	4 (0.2)	4 (0.2)
		P[8]	1517 (93.6)	1516 (93.6)
		P[9]	5 (0.3)	5 (0.3)
		P non-typable	31 (1.9)	31 (1.9)
		Total	1620 (100.0)	1619 (100.0)
Vaccinated	ELISA testing results (n, %) ^[3]	Positive	118 (7.3)	117 (7.4)
		Negative	1494 (92.7)	1465 (92.6)
		Total	1612 (100.0)	1582 (100.0)
	VP7(G type) results (n, %) ^[4]	G1	1 (0.8)	1 (0.9)
		G2	2 (1.7)	2 (1.7)
		G3	12 (10.2)	11 (9.4)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by vaccination status (Vaccinated and Unvaccinated).

^[4] The denominator is the number of patients with ELISA positive results, stratified by vaccination status (Vaccinated and Unvaccinated).

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Table 14.2.14. Rotavirus detection and typing results-By Vaccination status (Vaccinated and Unvaccinated) (Analysis Population) (Continued)

<i>Vaccination status</i>		<i>V260-079 Study Population (N=5624)</i>	<i>V260-079 Analysis Population (N=5594)</i>
	G4	1 (0.8)	1 (0.9)
	G6	1 (0.8)	1 (0.9)
	G8	62 (52.5)	62 (53.0)
	G9	36 (30.5)	36 (30.8)
	G11	0	0
	G12	0	0
	G non-typable	3 (2.5)	3 (2.6)
	Total	118 (100.0)	117 (100.0)
	VP4(P type) results (n, %) ^[4]		
	P[4]	4 (3.4)	4 (3.4)
	P[6]	1 (0.8)	1 (0.9)
	P[8]	110 (93.2)	109 (93.2)
	P[9]	0	0
	P non-typable	3 (2.5)	3 (2.6)
	Total	118 (100.0)	117 (100.0)
	ELISA testing results (n, %) ^[3]		
	Positive	1502 (37.4)	1502 (37.4)
	Negative	2510 (62.6)	2510 (62.6)
	Total	4012 (100.0)	4012 (100.0)
Unvaccinated	VP7(G type) results (n, %) ^[4]		
	G1	16 (1.1)	16 (1.1)
	G2	50 (3.3)	50 (3.3)
	G3	231 (15.4)	231 (15.4)
	G4	3 (0.2)	3 (0.2)
	G6	2 (0.1)	2 (0.1)
	G8	526 (35.0)	526 (35.0)
	G9	631 (42.0)	631 (42.0)
	G11	1 (0.1)	1 (0.1)
	G12	1 (0.1)	1 (0.1)
	G non-typable	41 (2.7)	41 (2.7)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by vaccination status (Vaccinated and Unvaccinated).

^[4] The denominator is the number of patients with ELISA positive results, stratified by vaccination status (Vaccinated and Unvaccinated).

Table 14.2.14. Rotavirus detection and typing results-By Vaccination status (Vaccinated and Unvaccinated) (Analysis Population) (Continued)

<i>Vaccination status</i>		<i>V260-079 Study Population (N=5624)</i>	<i>V260-079 Analysis Population (N=5594)</i>
	Total	1502 (100.0)	1502 (100.0)
VP4(P type) results (n, %) ^[4]	P[4]	59 (3.9)	59 (3.9)
	P[6]	3 (0.2)	3 (0.2)
	P[8]	1407 (93.7)	1407 (93.7)
	P[9]	5 (0.3)	5 (0.3)
	P non-typable	28 (1.9)	28 (1.9)
	Total	1502 (100.0)	1502 (100.0)

^[1] The denominator is the number of patients in study population or analysis population, respectively.

^[2] The denominator is the number of patients with ELISA positive results.

^[3] The denominator is the number of patients in study population or analysis population respectively, stratified by vaccination status (Vaccinated and Unvaccinated).

^[4] The denominator is the number of patients with ELISA positive results, stratified by vaccination status (Vaccinated and Unvaccinated).

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Table 14.2.15. Frequency of Rotavirus A G-P type combinations-By Age (<2 years and >=2 years) (Analysis Population)

Age	Types	P[4]	P[6]	P[8]	P[9]	Other P-type	P non-typable	Total
<2 years	G1	0	0	13 (1.2)	0	0	0	13 (1.2)
	G2	42 (3.9)	0	2 (0.2)	0	0	1 (0.1)	45 (4.1)
	G3	0	0	105 (9.7)	1 (0.1)	0	0	106 (9.8)
	G4	0	3 (0.3)	0	0	0	0	3 (0.3)
	G6	0	0	1 (0.1)	0	0	2 (0.2)	3 (0.3)
	G8	0	0	367 (33.8)	0	0	1 (0.1)	368 (33.9)
	G9	2 (0.2)	0	506 (46.6)	0	0	4 (0.4)	512 (47.1)
	G11	0	0	1 (0.1)	0	0	0	1 (0.1)
	G12	0	0	0	0	0	0	0
	Other G-type	0	0	0	0	0	0	0
	G non-typable	3 (0.3)	0	15 (1.4)	0	0	18 (1.7)	36 (3.3)
	Total	47 (4.3)	3 (0.3)	1010 (92.9)	1 (0.1)	0	26 (2.4)	1087 (100.0)
>=2 years	G1	0	0	4 (0.8)	0	0	0	4 (0.8)
	G2	7 (1.3)	0	0	0	0	0	7 (1.3)
	G3	0	0	131 (24.6)	4 (0.8)	0	1 (0.2)	136 (25.6)
	G4	0	1 (0.2)	0	0	0	0	1 (0.2)
	G6	0	0	0	0	0	0	0
	G8	0	0	218 (41.0)	0	0	2 (0.4)	220 (41.4)
	G9	7 (1.3)	0	147 (27.6)	0	0	1 (0.2)	155 (29.1)
	G11	0	0	0	0	0	0	0
	G12	0	0	1 (0.2)	0	0	0	1 (0.2)
	Other G-type	0	0	0	0	0	0	0
	G non-typable	2 (0.4)	0	5 (0.9)	0	0	1 (0.2)	8 (1.5)
	Total	16 (3.0)	1 (0.2)	506 (95.1)	4 (0.8)	0	5 (0.9)	532 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results, stratified by age groups (<2 years and >=2 years).

Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;

Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

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Table 14.2.16. Frequency of Rotavirus A G-P type combinations-By Regions (South and North) (Analysis Population)

<i>Regions*</i>	<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
South	G1	0	0	15 (1.5)	0	0	0	15 (1.5)
	G2	28 (2.7)	0	2 (0.2)	0	0	1 (0.1)	31 (3.0)
	G3	0	0	183 (17.8)	5 (0.5)	0	1 (0.1)	189 (18.3)
	G4	0	4 (0.4)	0	0	0	0	4 (0.4)
	G6	0	0	1 (0.1)	0	0	2 (0.2)	3 (0.3)
	G8	0	0	461 (44.8)	0	0	3 (0.3)	464 (45.0)
	G9	3 (0.3)	0	282 (27.4)	0	0	3 (0.3)	288 (28.0)
	G11	0	0	1 (0.1)	0	0	0	1 (0.1)
	G12	0	0	1 (0.1)	0	0	0	1 (0.1)
	Other G-type	0	0	0	0	0	0	0
	G non-typable	5 (0.5)	0	16 (1.6)	0	0	13 (1.3)	34 (3.3)
	Total	36 (3.5)	4 (0.4)	962 (93.4)	5 (0.5)	0	23 (2.2)	1030 (100.0)
North	G1	0	0	2 (0.3)	0	0	0	2 (0.3)
	G2	21 (3.6)	0	0	0	0	0	21 (3.6)
	G3	0	0	53 (9.0)	0	0	0	53 (9.0)
	G4	0	0	0	0	0	0	0
	G6	0	0	0	0	0	0	0
	G8	0	0	124 (21.1)	0	0	0	124 (21.1)
	G9	6 (1.0)	0	371 (63.0)	0	0	2 (0.3)	379 (64.3)
	G11	0	0	0	0	0	0	0
	G12	0	0	0	0	0	0	0
	Other G-type	0	0	0	0	0	0	0
	G non-typable	0	0	4 (0.7)	0	0	6 (1.0)	10 (1.7)
	Total	27 (4.6)	0	554 (94.1)	0	0	8 (1.4)	589 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results, stratified by region groups (South and North).

Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;

Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

* South (Anhui, Chongqing, Fujian, Guangdong, Henan (Xinyang), Hubei, Hunan, Jiangsu, Sichuan, Yunnan and Zhejiang); North (Beijing, Hebei, Henan (exclude Xinyang), Shaanxi and Shandong).

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Table 14.2.17. Frequency of Rotavirus A G-P type combinations-By Regions (East, Central and West) (Analysis Population)

<i>Regions*</i>	<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
East	G1	0	0	9 (1.3)	0	0	0	9 (1.3)
	G2	8 (1.2)	0	1 (0.1)	0	0	0	9 (1.3)
	G3	0	0	147 (21.8)	3 (0.4)	0	1 (0.1)	151 (22.4)
	G4	0	0	0	0	0	0	0
	G6	0	0	0	0	0	0	0
	G8	0	0	269 (40.0)	0	0	1 (0.1)	270 (40.1)
	G9	8 (1.2)	0	196 (29.1)	0	0	3 (0.4)	207 (30.8)
	G11	0	0	0	0	0	0	0
	G12	0	0	1 (0.1)	0	0	0	1 (0.1)
	Other G-type	0	0	0	0	0	0	0
	G non-typable	3 (0.4)	0	10 (1.5)	0	0	13 (1.9)	26 (3.9)
	Total	19 (2.8)	0	633 (94.1)	3 (0.4)	0	18 (2.7)	673 (100.0)
Central	G1	0	0	5 (1.3)	0	0	0	5 (1.3)
	G2	15 (3.8)	0	1 (0.3)	0	0	0	16 (4.1)
	G3	0	0	51 (13.0)	1 (0.3)	0	0	52 (13.3)
	G4	0	1 (0.3)	0	0	0	0	1 (0.3)
	G6	0	0	0	0	0	0	0
	G8	0	0	175 (44.6)	0	0	2 (0.5)	177 (45.2)
	G9	0	0	134 (34.2)	0	0	1 (0.3)	135 (34.4)
	G11	0	0	0	0	0	0	0
	G12	0	0	0	0	0	0	0
	Other G-type	0	0	0	0	0	0	0
	G non-typable	0	0	4 (1.0)	0	0	2 (0.5)	6 (1.5)
	Total	15 (3.8)	1 (0.3)	370 (94.4)	1 (0.3)	0	5 (1.3)	392 (100.0)
West	G1	0	0	3 (0.5)	0	0	0	3 (0.5)
	G2	26 (4.7)	0	0	0	0	1 (0.2)	27 (4.9)
	G3	0	0	38 (6.9)	1 (0.2)	0	0	39 (7.0)
	G4	0	3 (0.5)	0	0	0	0	3 (0.5)
	G6	0	0	1 (0.2)	0	0	2 (0.4)	3 (0.5)

The denominator is the number of patients from the analysis population with ELISA positive results, stratified by region groups (East, Central and West).

Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;

Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

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Table 14.2.17. Frequency of Rotavirus A G-P type combinations-By Regions (East, Central and West) (Analysis Population)
(Continued)

<i>Regions*</i>	<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
	G8	0	0	141 (25.5)	0	0	0	141 (25.5)
	G9	1 (0.2)	0	323 (58.3)	0	0	1 (0.2)	325 (58.7)
	G11	0	0	1 (0.2)	0	0	0	1 (0.2)
	G12	0	0	0	0	0	0	0
	Other G-type	0	0	0	0	0	0	0
	G non-typable	2 (0.4)	0	6 (1.1)	0	0	4 (0.7)	12 (2.2)
	Total	29 (5.2)	3 (0.5)	513 (92.6)	1 (0.2)	0	8 (1.4)	554 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results, stratified by region groups (East, Central and West).

Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;

Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

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**Table 14.2.18. Frequency of Rotavirus A G-P type combinations-By Vaccination Status (Vaccinated and Unvaccinated)
(Analysis Population)**

<i>Vaccination status</i>	<i>Types</i>	<i>P[4]</i>	<i>P[6]</i>	<i>P[8]</i>	<i>P[9]</i>	<i>Other P-type</i>	<i>P non-typable</i>	<i>Total</i>
Vaccinated	G1	0	0	1 (0.9)	0	0	0	1 (0.9)
	G2	2 (1.7)	0	0	0	0	0	2 (1.7)
	G3	0	0	11 (9.4)	0	0	0	11 (9.4)
	G4	0	1 (0.9)	0	0	0	0	1 (0.9)
	G6	0	0	1 (0.9)	0	0	0	1 (0.9)
	G8	0	0	61 (52.1)	0	0	1 (0.9)	62 (53.0)
	G9	1 (0.9)	0	34 (29.1)	0	0	1 (0.9)	36 (30.8)
	G11	0	0	0	0	0	0	0
	G12	0	0	0	0	0	0	0
	Other G-type	0	0	0	0	0	0	0
	G non-typable	1 (0.9)	0	1 (0.9)	0	0	1 (0.9)	3 (2.6)
	Total	4 (3.4)	1 (0.9)	109 (93.2)	0	0	3 (2.6)	117 (100.0)
Unvaccinated	G1	0	0	16 (1.1)	0	0	0	16 (1.1)
	G2	47 (3.1)	0	2 (0.1)	0	0	1 (0.1)	50 (3.3)
	G3	0	0	225 (15.0)	5 (0.3)	0	1 (0.1)	231 (15.4)
	G4	0	3 (0.2)	0	0	0	0	3 (0.2)
	G6	0	0	0	0	0	2 (0.1)	2 (0.1)
	G8	0	0	524 (34.9)	0	0	2 (0.1)	526 (35.0)
	G9	8 (0.5)	0	619 (41.2)	0	0	4 (0.3)	631 (42.0)
	G11	0	0	1 (0.1)	0	0	0	1 (0.1)
	G12	0	0	1 (0.1)	0	0	0	1 (0.1)
	Other G-type	0	0	0	0	0	0	0
	G non-typable	4 (0.3)	0	19 (1.3)	0	0	18 (1.2)	41 (2.7)
	Total	59 (3.9)	3 (0.2)	1407 (93.7)	5 (0.3)	0	28 (1.9)	1502 (100.0)

The denominator is the number of patients from the analysis population with ELISA positive results, stratified by vaccination status (Vaccinated and Unvaccinated).

Other G-type: Types other than G1, G2, G3, G4, G6, G8, G9, G11, G12 are classified as other G-type;

Other P-type: Types other than P4, P6, P8, P9 are classified as other P-type.

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Table 14.2.19. RV Test Result-Symptom onset seasons: 2020/10-2021/3 (Analysis Population)

<i>Symptom onset seasons-months*</i>		<i>Analysis Population (N=5594)</i>	
Total	ELISA testing results (n, %) ^[1]	Positive	422 (65.1)
		Negative	226 (34.9)
		Total	648 (100.0)
October	ELISA testing results (n, %) ^[2]	Positive	3 (14.3)
		Negative	18 (85.7)
		Total	21 (100.0)
November	ELISA testing results (n, %) ^[2]	Positive	15 (23.1)
		Negative	50 (76.9)
		Total	65 (100.0)
December	ELISA testing results (n, %) ^[2]	Positive	95 (68.3)
		Negative	44 (31.7)
		Total	139 (100.0)
January	ELISA testing results (n, %) ^[2]	Positive	132 (71.7)
		Negative	52 (28.3)
		Total	184 (100.0)
February	ELISA testing results (n, %) ^[2]	Positive	95 (74.2)
		Negative	33 (25.8)
		Total	128 (100.0)
March	ELISA testing results (n, %) ^[2]	Positive	82 (73.9)
		Negative	29 (26.1)
		Total	111 (100.0)

[1] The denominator is the number of patients in analysis population for the current symptom onset season.

* Stratify by month based on patients' enrollment dates.

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Table 14.2.20. RV Test Result-Symptom onset seasons: 2021/10-2022/4 (Analysis Population)

<i>Symptom onset seasons-months*</i>		<i>Analysis Population (N=5594)</i>	
Total	ELISA testing results (n, %) ^[1]	Positive	492 (28.4)
		Negative	1241 (71.6)
		Total	1733 (100.0)
October	ELISA testing results (n, %) ^[2]	Positive	14 (13.0)
		Negative	94 (87.0)
		Total	108 (100.0)
November	ELISA testing results (n, %) ^[2]	Positive	24 (10.1)
		Negative	213 (89.9)
		Total	237 (100.0)
December	ELISA testing results (n, %) ^[2]	Positive	71 (19.3)
		Negative	296 (80.7)
		Total	367 (100.0)
January	ELISA testing results (n, %) ^[2]	Positive	74 (29.2)
		Negative	179 (70.8)
		Total	253 (100.0)
February	ELISA testing results (n, %) ^[2]	Positive	109 (44.1)
		Negative	138 (55.9)
		Total	247 (100.0)
March	ELISA testing results (n, %) ^[2]	Positive	149 (45.0)
		Negative	182 (55.0)
		Total	331 (100.0)
April	ELISA testing results (n, %) ^[2]	Positive	51 (26.8)
		Negative	139 (73.2)
		Total	190 (100.0)

[1] The denominator is the number of patients in analysis population for the current symptom onset season.

* Stratify by month based on patients' enrollment dates.

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Table 14.2.21. RV Test Result-Symptom onset seasons: 2022/10-2023/4 (Analysis Population)

<i>Symptom onset seasons-months*</i>		<i>Analysis Population (N=5594)</i>	
Total	ELISA testing results (n, %) ^[1]	Positive	225 (14.9)
		Negative	1281 (85.1)
		Total	1506 (100.0)
October	ELISA testing results (n, %) ^[2]	Positive	6 (4.0)
		Negative	145 (96.0)
		Total	151 (100.0)
November	ELISA testing results (n, %) ^[2]	Positive	7 (4.0)
		Negative	170 (96.0)
		Total	177 (100.0)
December	ELISA testing results (n, %) ^[2]	Positive	4 (4.9)
		Negative	77 (95.1)
		Total	81 (100.0)
January	ELISA testing results (n, %) ^[2]	Positive	15 (15.8)
		Negative	80 (84.2)
		Total	95 (100.0)
February	ELISA testing results (n, %) ^[2]	Positive	66 (18.9)
		Negative	283 (81.1)
		Total	349 (100.0)
March	ELISA testing results (n, %) ^[2]	Positive	81 (22.6)
		Negative	278 (77.4)
		Total	359 (100.0)
April	ELISA testing results (n, %) ^[2]	Positive	46 (15.6)
		Negative	248 (84.4)
		Total	294 (100.0)

[1] The denominator is the number of patients in analysis population for the current symptom onset season.

* Stratify by month based on patients' enrollment dates.

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Table 14.2.22. RV Test Result-Symptom onset seasons: 2024/10-2025/4 (Analysis Population)

<i>Symptom onset seasons-months*</i>		<i>Analysis Population (N=5594)</i>	
Total	ELISA testing results (n, %) ^[1]	Positive	480 (28.1)
		Negative	1227 (71.9)
		Total	1707 (100.0)
October	ELISA testing results (n, %) ^[2]	Positive	9 (4.3)
		Negative	202 (95.7)
		Total	211 (100.0)
November	ELISA testing results (n, %) ^[2]	Positive	15 (6.6)
		Negative	213 (93.4)
		Total	228 (100.0)
December	ELISA testing results (n, %) ^[2]	Positive	21 (8.4)
		Negative	229 (91.6)
		Total	250 (100.0)
January	ELISA testing results (n, %) ^[2]	Positive	61 (23.8)
		Negative	195 (76.2)
		Total	256 (100.0)
February	ELISA testing results (n, %) ^[2]	Positive	147 (42.5)
		Negative	199 (57.5)
		Total	346 (100.0)
March	ELISA testing results (n, %) ^[2]	Positive	167 (52.2)
		Negative	153 (47.8)
		Total	320 (100.0)
April	ELISA testing results (n, %) ^[2]	Positive	60 (62.5)
		Negative	36 (37.5)
		Total	96 (100.0)

[1] The denominator is the number of patients in analysis population for the current symptom onset season.

* Stratify by month based on patients' enrollment dates.

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Table 14.2.23. RV Test Result-By Age(<2 years and >=2 years) (Analysis Population)

<i>Subgroup-Age</i>		<i>Analysis Population (N=5594)</i>	
<2 years	ELISA testing results (n, %) ^[1]	Positive	1087 (25.7)
		Negative	3138 (74.3)
		Total	4225 (100.0)
>=2 years	ELISA testing results (n, %) ^[1]	Positive	532 (38.9)
		Negative	837 (61.1)
		Total	1369 (100.0)

[1] The denominator is the number of patients in analysis population, stratified by age groups (<2 years and >=2 years).

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Table 14.2.24. RV Test Result-By Region (South and North) (Analysis Population)

<i>Subgroup-Regions*</i>		<i>Analysis Population (N=5594)</i>	
South	ELISA testing results (n, %) ^[1]	Positive	1030 (23.4)
		Negative	3380 (76.6)
		Total	4410 (100.0)
North	ELISA testing results (n, %) ^[1]	Positive	589 (49.7)
		Negative	595 (50.3)
		Total	1184 (100.0)

[1] The denominator is the number of patients in analysis population, stratified by region groups (South and North).

* South (Anhui, Chongqing, Fujian, Guangdong, Henan (Xinyang), Hubei, Hunan, Jiangsu, Sichuan, Yunnan and Zhejiang); North (Beijing, Hebei, Henan (exclude Xinyang), Shaanxi and Shandong).

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Table 14.2.25. RV Test Result-By Region (East, Central and West) (Analysis Population)

<i>Subgroup-Regions*</i>		<i>Analysis Population (N=5594)</i>	
East	ELISA testing results (n, %) ^[1]	Positive	673 (25.4)
		Negative	1980 (74.6)
		Total	2653 (100.0)
Central	ELISA testing results (n, %) ^[1]	Positive	392 (28.5)
		Negative	985 (71.5)
		Total	1377 (100.0)
West	ELISA testing results (n, %) ^[1]	Positive	554 (35.4)
		Negative	1010 (64.6)
		Total	1564 (100.0)

[1] The denominator is the number of patients in analysis population, stratified by region groups (East, Central and West).

* East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

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Table 14.2.26. RV Test Result-By Vaccination Status (Vaccinated and Unvaccinated) (Analysis Population)

<i>Subgroup-Vaccination Status</i>		<i>Analysis Population (N=5594)</i>	
Vaccinated	ELISA testing results (n, %) ^[1]	Positive	117 (7.4)
		Negative	1465 (92.6)
		Total	1582 (100.0)
Unvaccinated	ELISA testing results (n, %) ^[1]	Positive	1502 (37.4)
		Negative	2510 (62.6)
		Total	4012 (100.0)

[1] The denominator is the number of patients in analysis population, stratified by vaccination status (Vaccinated and Unvaccinated).

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Table 14.3.1. Crude vaccine effectiveness against RVGE cases (Analysis Population) (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	117 (7.2)	1465 (36.9)	1582 (28.3)	86.65% (83.72%, 89.06%)
Unvaccinated	1502 (92.8)	2510 (63.1)	4012 (71.7)	
Total	1619 (100.0)	3975 (100.0)	5594 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

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Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (Analysis Population)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Age of onset group	<=11 months	Vaccinated	21 (7.4)	520 (35.1)	541 (30.7)	85.19% (76.60%, 90.62%)
		Unvaccinated	262 (92.6)	961 (64.9)	1223 (69.3)	
		Total	283 (100.0)	1481 (100.0)	1764 (100.0)	
	12-23 months	Vaccinated	58 (7.2)	655 (39.5)	713 (29.0)	88.11% (84.19%, 91.05%)
		Unvaccinated	746 (92.8)	1002 (60.5)	1748 (71.0)	
		Total	804 (100.0)	1657 (100.0)	2461 (100.0)	
	24-35 months	Vaccinated	23 (8.4)	182 (37.4)	205 (27.0)	84.69% (75.64%, 90.38%)
		Unvaccinated	251 (91.6)	304 (62.6)	555 (73.0)	
		Total	274 (100.0)	486 (100.0)	760 (100.0)	
	>=36 months	Vaccinated	15 (5.8)	108 (30.8)	123 (20.2)	86.11% (75.48%, 92.13%)
		Unvaccinated	243 (94.2)	243 (69.2)	486 (79.8)	
		Total	258 (100.0)	351 (100.0)	609 (100.0)	
Birth seasons	RV peak season ^[1]	Vaccinated	68 (7.2)	870 (37.6)	938 (28.8)	87.16% (83.34%, 90.11%)
		Unvaccinated	879 (92.8)	1444 (62.4)	2323 (71.2)	
		Total	947 (100.0)	2314 (100.0)	3261 (100.0)	
	Non-RV peak season	Vaccinated	49 (7.3)	595 (35.8)	644 (27.6)	85.91% (80.83%, 89.64%)
		Unvaccinated	623 (92.7)	1066 (64.2)	1689 (72.4)	
		Total	672 (100.0)	1661 (100.0)	2333 (100.0)	
Residence location	Urban	Vaccinated	78 (8.0)	1030 (39.5)	1108 (30.9)	86.76% (83.10%, 89.63%)
		Unvaccinated	902 (92.0)	1577 (60.5)	2479 (69.1)	
		Total	980 (100.0)	2607 (100.0)	3587 (100.0)	
	Rural	Vaccinated	38 (6.0)	434 (31.7)	472 (23.6)	86.34% (80.67%, 90.35%)
		Unvaccinated				
		Total				

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (Analysis Population) (Continued)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Regions of study hospitals ^[2]	East	Unvaccinated	598 (94.0)	933 (68.3)	1531 (76.4)	85.75% (80.91%, 89.37%)
		Total	636 (100.0)	1367 (100.0)	2003 (100.0)	
		Vaccinated	54 (8.0)	752 (38.0)	806 (30.4)	
	Central	Unvaccinated	619 (92.0)	1228 (62.0)	1847 (69.6)	91.32% (85.64%, 94.75%)
		Total	673 (100.0)	1980 (100.0)	2653 (100.0)	
		Vaccinated	17 (4.3)	338 (34.3)	355 (25.8)	
	West	Unvaccinated	375 (95.7)	647 (65.7)	1022 (74.2)	84.67% (78.72%, 88.95%)
		Total	392 (100.0)	985 (100.0)	1377 (100.0)	
		Vaccinated	46 (8.3)	375 (37.1)	421 (26.9)	
	Clinical setting	Unvaccinated	508 (91.7)	635 (62.9)	1143 (73.1)	87.37% (84.30%, 89.84%)
		Total	554 (100.0)	1010 (100.0)	1564 (100.0)	
		Vaccinated	97 (6.7)	1244 (36.4)	1341 (27.6)	
Symptom onset seasons ^[3]	2020/10-2021/3	Unvaccinated	1342 (93.3)	2174 (63.6)	3516 (72.4)	81.00% (68.83%, 88.41%)
		Total	1439 (100.0)	3418 (100.0)	4857 (100.0)	
		Vaccinated	20 (11.1)	221 (39.7)	241 (32.7)	
	2021/10-2022/4	Unvaccinated	160 (88.9)	336 (60.3)	496 (67.3)	84.13% (66.90%, 92.40%)
		Total	180 (100.0)	557 (100.0)	737 (100.0)	
		Vaccinated	10 (2.4)	30 (13.3)	40 (6.2)	
		Unvaccinated	412 (97.6)	196 (86.7)	608 (93.8)	75.22% (66.10%, 81.89%)
		Total	422 (100.0)	226 (100.0)	648 (100.0)	
		Vaccinated	51 (10.4)	395 (31.8)	446 (25.7)	
		Unvaccinated	441 (89.6)	846 (68.2)	1287 (74.3)	
		Total				
		Vaccinated				

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (Analysis Population) (Continued)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			492 (100.0)	1241 (100.0)	1733 (100.0)	
2022/10-2023/4	Vaccinated	Unvaccinated	29 (12.9)	552 (43.1)	581 (38.6)	80.46% (70.69%, 86.97%)
			196 (87.1)	729 (56.9)	925 (61.4)	
			225 (100.0)	1281 (100.0)	1506 (100.0)	
	Vaccinated	Unvaccinated	27 (5.6)	488 (39.8)	515 (30.2)	90.97% (86.47%, 93.98%)
			453 (94.4)	739 (60.2)	1192 (69.8)	
			480 (100.0)	1227 (100.0)	1707 (100.0)	
Gender	Male	Vaccinated	69 (6.9)	860 (36.1)	929 (27.5)	86.90% (83.03%, 89.88%)
			932 (93.1)	1522 (63.9)	2454 (72.5)	
			1001 (100.0)	2382 (100.0)	3383 (100.0)	
	Female	Vaccinated	48 (7.8)	605 (38.0)	653 (29.5)	86.25% (81.22%, 89.93%)
			570 (92.2)	988 (62.0)	1558 (70.5)	
			618 (100.0)	1593 (100.0)	2211 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.3.3. Demographic and clinical characteristics of RVGE case and control groups (Analysis Population)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Age of onset (in months)	n (nmiss)	1619 (0)	3975 (0)	5594 (0)
	Mean (Std)	23.20 (14.297)	17.88 (12.099)	19.42 (12.998)
	Median	19.30	14.40	15.70
	Q1, Q3	13.80, 28.10	9.50, 21.80	10.50, 23.70
	Min, Max	3.8, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	283 (17.5)	1481 (37.3)	1764 (31.5)
	12-23 months	804 (49.7)	1657 (41.7)	2461 (44.0)
	24-35 months	274 (16.9)	486 (12.2)	760 (13.6)
	>=36 months	258 (15.9)	351 (8.8)	609 (10.9)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	947 (58.5)	2314 (58.2)	3261 (58.3)
	Non-RV peak season	672 (41.5)	1661 (41.8)	2333 (41.7)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)
Residence location (n, %)	Urban	980 (60.5)	2607 (65.6)	3587 (64.1)
	Rural	636 (39.3)	1367 (34.4)	2003 (35.8)
	Missing	3 (0.2)	1 (0.0)	4 (0.1)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)
Regions of study hospitals (n, %) ^[2]	East	673 (41.6)	1980 (49.8)	2653 (47.4)
	Central	392 (24.2)	985 (24.8)	1377 (24.6)
	West	554 (34.2)	1010 (25.4)	1564 (28.0)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)
Clinical settings (n, %)	Inpatient	1439 (88.9)	3418 (86.0)	4857 (86.8)
	Outpatient	180 (11.1)	557 (14.0)	737 (13.2)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.3.3. Demographic and clinical characteristics of RVGE case and control groups (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	422 (26.1)	226 (5.7)	648 (11.6)
	2021/10-2022/4	492 (30.4)	1241 (31.2)	1733 (31.0)
	2022/10-2023/4	225 (13.9)	1281 (32.2)	1506 (26.9)
	2024/10-2025/4	480 (29.6)	1227 (30.9)	1707 (30.5)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)
Gender (n, %)	Male	1001 (61.8)	2382 (59.9)	3383 (60.5)
	Female	618 (38.2)	1593 (40.1)	2211 (39.5)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)
College and above for either parent's education level (n, %) No	Yes	425 (26.3)	1072 (27.0)	1497 (26.8)
	Yes	760 (46.9)	2643 (66.5)	3403 (60.8)
	Missing	434 (26.8)	260 (6.5)	694 (12.4)
	Total	1619 (100.0)	3975 (100.0)	5594 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

[1] October to April of the following year.

[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.3.4. Univariate Logistic Regression (Analysis Population)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Age of onset (in months) (Continuous)	0.029	<.001	1.030 (1.025, 1.034)
Birth seasons (RV peak season vs Non-RV peak season)	0.011	0.848	1.012 (0.900, 1.137)
Residence location (Urban vs Rural)	-0.213	<.001	0.808 (0.717, 0.910)
Regions of study hospitals (Central vs East)	0.158	0.034	1.171 (1.012, 1.355)
Regions of study hospitals (West vs East)	0.479	<.001	1.614 (1.409, 1.848)
Clinical setting (Inpatient vs Outpatient)	0.264	0.004	1.303 (1.089, 1.558)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.563	<.001	4.773 (3.935, 5.789)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.013	0.860	1.013 (0.874, 1.176)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.801	<.001	0.449 (0.376, 0.536)
Gender (Male vs Female)	0.080	0.187	1.083 (0.962, 1.220)
Received ROTATEQ vaccination (Yes vs No)	-2.014	<.001	0.133 (0.109, 0.163)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Table 14.3.5. Adjusted vaccine effectiveness against RVGE cases (Analysis Population)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Age of onset (in months) (Continuous) ^[1]	0.041	<.001	1.041 (1.036, 1.047)	
Residence location (Urban vs Rural) ^[1]	-0.181	0.010	0.834 (0.727, 0.958)	
Regions of study hospitals (Central vs East) ^[1]	0.234	0.006	1.264 (1.070, 1.491)	
Regions of study hospitals (West vs East) ^[1]	0.578	<.001	1.782 (1.523, 2.085)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.668	<.001	1.949 (1.573, 2.415)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	1.774	<.001	5.894 (4.731, 7.342)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.273	0.001	1.314 (1.112, 1.554)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.590	<.001	0.555 (0.458, 0.672)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.732	<.001	0.177 (0.144, 0.218)	82.31% (78.23%, 85.63%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.3.4, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Unconditional Multivariate logistic regression was performed using a sample size of 5590 (including 1616 cases and 3974 controls).

Table 14.4.1.1. G1-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	1 (5.9)	1465 (36.9)	1466 (36.7)	89.29% (19.17%, 98.58%)
Unvaccinated	16 (94.1)	2510 (63.1)	2526 (63.3)	
Total	17 (100.0)	3975 (100.0)	3992 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.2. G2-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	2 (3.8)	1465 (36.9)	1467 (36.4)	93.15% (71.79%, 98.33%)
Unvaccinated	50 (96.2)	2510 (63.1)	2560 (63.6)	
Total	52 (100.0)	3975 (100.0)	4027 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.3. G3-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	11 (4.5)	1465 (36.9)	1476 (35.0)	91.84% (85.01%, 95.56%)
Unvaccinated	231 (95.5)	2510 (63.1)	2741 (65.0)	
Total	242 (100.0)	3975 (100.0)	4217 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.4. G4-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	1 (25.0)	1465 (36.9)	1466 (36.8)	42.89% (-449.54%, 94.06%)
Unvaccinated	3 (75.0)	2510 (63.1)	2513 (63.2)	
Total	4 (100.0)	3975 (100.0)	3979 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.5. G6-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	1 (33.3)	1465 (36.9)	1466 (36.9)	14.33% (-845.55%, 92.24%)
Unvaccinated	2 (66.7)	2510 (63.1)	2512 (63.1)	
Total	3 (100.0)	3975 (100.0)	3978 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.6. G8-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	62 (10.5)	1465 (36.9)	1527 (33.5)	79.80% (73.52%, 84.60%)
Unvaccinated	526 (89.5)	2510 (63.1)	3036 (66.5)	
Total	588 (100.0)	3975 (100.0)	4563 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.7. G9-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	36 (5.4)	1465 (36.9)	1501 (32.3)	90.23% (86.24%, 93.06%)
Unvaccinated	631 (94.6)	2510 (63.1)	3141 (67.7)	
Total	667 (100.0)	3975 (100.0)	4642 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.8. G11-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
Unvaccinated	1 (100.0)	2510 (63.1)	2511 (63.2)	
Total	1 (100.0)	3975 (100.0)	3976 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.1.9. G12-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
Unvaccinated	1 (100.0)	2510 (63.1)	2511 (63.2)	
Total	1 (100.0)	3975 (100.0)	3976 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.1.10. P[4]-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	4 (6.3)	1465 (36.9)	1469 (36.4)	88.38% (67.96%, 95.79%)
Unvaccinated	59 (93.7)	2510 (63.1)	2569 (63.6)	
Total	63 (100.0)	3975 (100.0)	4038 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.11. P[6]-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	1 (25.0)	1465 (36.9)	1466 (36.8)	42.89% (-449.54%, 94.06%)
Unvaccinated	3 (75.0)	2510 (63.1)	2513 (63.2)	
Total	4 (100.0)	3975 (100.0)	3979 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.12. P[8]-Analysis Population (Unadjusted)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	109 (7.2)	1465 (36.9)	1574 (28.7)	86.73% (83.70%, 89.19%)
Unvaccinated	1407 (92.8)	2510 (63.1)	3917 (71.3)	
Total	1516 (100.0)	3975 (100.0)	5491 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.1.13. P[9]-Analysis Population (Unadjusted)

	<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>	<i>VE</i> (%, 95% CI)
Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
Unvaccinated	5 (100.0)	2510 (63.1)	2515 (63.2)	
Total	5 (100.0)	3975 (100.0)	3980 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.1.14. All G/P type combinations-Analysis Population (Unadjusted)

Combination Type		Case Group (RV +)	Control Group (RV -)	Total	VE
		N (%)	N (%)	N (%)	(%, 95% CI)
G1P[8]	Vaccinated	1 (5.9)	1465 (36.9)	1466 (36.7)	89.29% (19.17%, 98.58%)
	Unvaccinated	16 (94.1)	2510 (63.1)	2526 (63.3)	
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)	
G2P[4]	Vaccinated	2 (4.1)	1465 (36.9)	1467 (36.5)	92.71% (69.94%, 98.23%)
	Unvaccinated	47 (95.9)	2510 (63.1)	2557 (63.5)	
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)	
G2P[8]	Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
	Unvaccinated	2 (100.0)	2510 (63.1)	2512 (63.2)	
	Total	2 (100.0)	3975 (100.0)	3977 (100.0)	
G3P[8]	Vaccinated	11 (4.7)	1465 (36.9)	1476 (35.1)	91.62% (84.60%, 95.44%)
	Unvaccinated	225 (95.3)	2510 (63.1)	2735 (64.9)	
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)	
G3P[9]	Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
	Unvaccinated	5 (100.0)	2510 (63.1)	2515 (63.2)	
	Total	5 (100.0)	3975 (100.0)	3980 (100.0)	
G4P[6]	Vaccinated	1 (25.0)	1465 (36.9)	1466 (36.8)	42.89% (-449.54%, 94.06%)
	Unvaccinated	3 (75.0)	2510 (63.1)	2513 (63.2)	
	Total	4 (100.0)	3975 (100.0)	3979 (100.0)	
G6P[8]	Vaccinated	1 (100.0)	1465 (36.9)	1466 (36.9)	NA*
	Unvaccinated	0	2510 (63.1)	2510 (63.1)	
	Total	1 (100.0)	3975 (100.0)	3976 (100.0)	
G8P[8]	Vaccinated	61 (10.4)	1465 (36.9)	1526 (33.5)	80.05% (73.80%, 84.82%)
	Unvaccinated	524 (89.6)	2510 (63.1)	3034 (66.5)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.1.14. All G/P type combinations-Analysis Population (Unadjusted) (Continued)

Combination Type		Case Group (RV +)	Control Group (RV -)	Total	VE
		N (%)	N (%)	N (%)	(%, 95% CI)
Total		585 (100.0)	3975 (100.0)	4560 (100.0)	
G9P[4]	Vaccinated	1 (11.1)	1465 (36.9)	1466 (36.8)	78.58% (-71.40%, 97.32%)
	Unvaccinated	8 (88.9)	2510 (63.1)	2518 (63.2)	
	Total	9 (100.0)	3975 (100.0)	3984 (100.0)	
G9P[8]	Vaccinated	34 (5.2)	1465 (36.9)	1499 (32.4)	90.59% (86.63%, 93.38%)
	Unvaccinated	619 (94.8)	2510 (63.1)	3129 (67.6)	
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)	
G11P[8]	Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
	Unvaccinated	1 (100.0)	2510 (63.1)	2511 (63.2)	
	Total	1 (100.0)	3975 (100.0)	3976 (100.0)	
G12P[8]	Vaccinated	0	1465 (36.9)	1465 (36.8)	NA*
	Unvaccinated	1 (100.0)	2510 (63.1)	2511 (63.2)	
	Total	1 (100.0)	3975 (100.0)	3976 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
G1	Age of onset group	<=11 months	Vaccinated	0	520 (35.1)	NA*
			Unvaccinated	4 (100.0)	961 (64.9)	
			Total	4 (100.0)	1481 (100.0)	
		12-23 months	Vaccinated	1 (11.1)	655 (39.5)	80.88% (-53.24%, 97.61%)
			Unvaccinated	8 (88.9)	1002 (60.5)	
			Total	9 (100.0)	1657 (100.0)	
		24-35 months	Vaccinated	0	182 (37.4)	NA*
			Unvaccinated	2 (100.0)	304 (62.6)	
			Total	2 (100.0)	486 (100.0)	
		>=36 months	Vaccinated	0	108 (30.8)	NA*
			Unvaccinated	2 (100.0)	243 (69.2)	
			Total	2 (100.0)	351 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	1 (11.1)	870 (37.6)	79.25% (-66.16%, 97.41%)
			Unvaccinated	8 (88.9)	1444 (62.4)	
			Total	9 (100.0)	2314 (100.0)	
		Non-RV peak season	Vaccinated	0	595 (35.8)	NA*
			Unvaccinated	8 (100.0)	1066 (64.2)	
			Total	8 (100.0)	1661 (100.0)	
	Residence location	Urban	Vaccinated	0	1030 (39.5)	NA*

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Regions of study hospitals ^[2]	Rural	Unvaccinated	6 (100.0)	1577 (60.5)	1583 (60.6)	78.50% (-68.46%, 97.26%)
		Total	6 (100.0)	2607 (100.0)	2613 (100.0)	
		Vaccinated	1 (9.1)	434 (31.7)	435 (31.6)	
	East	Unvaccinated	10 (90.9)	933 (68.3)	943 (68.4)	NA*
		Total	11 (100.0)	1367 (100.0)	1378 (100.0)	
		Vaccinated	0	752 (38.0)	752 (37.8)	
	Central	Unvaccinated	9 (100.0)	1228 (62.0)	1237 (62.2)	NA*
		Total	9 (100.0)	1980 (100.0)	1989 (100.0)	
		Vaccinated	0	338 (34.3)	338 (34.1)	
	West	Unvaccinated	5 (100.0)	647 (65.7)	652 (65.9)	15.33% (-836.89%, 92.35%)
		Total	5 (100.0)	985 (100.0)	990 (100.0)	
		Vaccinated	1 (33.3)	375 (37.1)	376 (37.1)	
Clinical setting	Inpatient	Unvaccinated	2 (66.7)	635 (62.9)	637 (62.9)	87.51% (4.96%, 98.36%)
		Total	3 (100.0)	1010 (100.0)	1013 (100.0)	
		Vaccinated	1 (6.7)	1244 (36.4)	1245 (36.3)	
	Outpatient	Unvaccinated	14 (93.3)	2174 (63.6)	2188 (63.7)	NA*
		Total	15 (100.0)	3418 (100.0)	3433 (100.0)	
		Vaccinated	0	221 (39.7)	221 (39.5)	
		Unvaccinated	2 (100.0)	336 (60.3)	338 (60.5)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			2 (100.0)	557 (100.0)	559 (100.0)	
Symptom onset seasons ^[3]	2020/10-2021/3	Vaccinated	0	30 (13.3)	30 (13.3)	NA*
		Unvaccinated	0	196 (86.7)	196 (86.7)	
		Total	0	226 (100.0)	226 (100.0)	
	2021/10-2022/4	Vaccinated	0	395 (31.8)	395 (31.7)	NA*
		Unvaccinated	6 (100.0)	846 (68.2)	852 (68.3)	
		Total	6 (100.0)	1241 (100.0)	1247 (100.0)	
	2022/10-2023/4	Vaccinated	0	552 (43.1)	552 (42.9)	NA*
		Unvaccinated	5 (100.0)	729 (56.9)	734 (57.1)	
		Total	5 (100.0)	1281 (100.0)	1286 (100.0)	
	2024/10-2025/4	Vaccinated	1 (16.7)	488 (39.8)	489 (39.7)	69.71% (-160.03%, 96.47%)
		Unvaccinated	5 (83.3)	739 (60.2)	744 (60.3)	
		Total	6 (100.0)	1227 (100.0)	1233 (100.0)	
Gender	Male	Vaccinated	1 (7.1)	860 (36.1)	861 (35.9)	86.38% (-4.25%, 98.22%)
		Unvaccinated	13 (92.9)	1522 (63.9)	1535 (64.1)	
		Total	14 (100.0)	2382 (100.0)	2396 (100.0)	
	Female	Vaccinated	0	605 (38.0)	605 (37.9)	NA*
		Unvaccinated	3 (100.0)	988 (62.0)	991 (62.1)	
		Total	3 (100.0)	1593 (100.0)	1596 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
G2	Age of onset group	<=11 months	Vaccinated	0	520 (35.1)	NA*
			Unvaccinated	14 (100.0)	961 (64.9)	
			Total	14 (100.0)	1481 (100.0)	
		12-23 months	Vaccinated	2 (6.5)	655 (39.5)	89.45% (55.64%, 97.49%)
			Unvaccinated	29 (93.5)	1002 (60.5)	
			Total	31 (100.0)	1657 (100.0)	
	24-35 months	Vaccinated	0	182 (37.4)	182 (37.1)	NA*
			Unvaccinated	5 (100.0)	304 (62.6)	
			Total	5 (100.0)	486 (100.0)	
		>=36 months	Vaccinated	0	108 (30.8)	NA*
			Unvaccinated	2 (100.0)	243 (69.2)	
			Total	2 (100.0)	351 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	2 (8.3)	870 (37.6)	84.91% (35.67%, 96.46%)
			Unvaccinated	22 (91.7)	1444 (62.4)	
			Total	24 (100.0)	2314 (100.0)	
		Non-RV peak season	Vaccinated	0	595 (35.8)	NA*
			Unvaccinated	28 (100.0)	1066 (64.2)	
			Total	28 (100.0)	1661 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Vaccinated	2 (7.1)	1030 (39.5)	1032 (39.2)	88.21% (50.26%, 97.21%)
		Unvaccinated	26 (92.9)	1577 (60.5)	1603 (60.8)	
		Total	28 (100.0)	2607 (100.0)	2635 (100.0)	
	Rural	Vaccinated	0	434 (31.7)	434 (31.2)	NA*
		Unvaccinated	24 (100.0)	933 (68.3)	957 (68.8)	
		Total	24 (100.0)	1367 (100.0)	1391 (100.0)	
Regions of study hospitals ^[2]	East	Vaccinated	0	752 (38.0)	752 (37.8)	NA*
		Unvaccinated	9 (100.0)	1228 (62.0)	1237 (62.2)	
		Total	9 (100.0)	1980 (100.0)	1989 (100.0)	
	Central	Vaccinated	1 (6.3)	338 (34.3)	339 (33.9)	87.23% (2.97%, 98.32%)
		Unvaccinated	15 (93.8)	647 (65.7)	662 (66.1)	
		Total	16 (100.0)	985 (100.0)	1001 (100.0)	
	West	Vaccinated	1 (3.7)	375 (37.1)	376 (36.3)	93.49% (51.81%, 99.12%)
		Unvaccinated	26 (96.3)	635 (62.9)	661 (63.7)	
		Total	27 (100.0)	1010 (100.0)	1037 (100.0)	
Clinical setting	Inpatient	Vaccinated	1 (2.4)	1244 (36.4)	1245 (36.0)	95.63% (68.18%, 99.40%)
		Unvaccinated	40 (97.6)	2174 (63.6)	2214 (64.0)	
		Total	41 (100.0)	3418 (100.0)	3459 (100.0)	
	Outpatient	Vaccinated	1 (9.1)	221 (39.7)	222 (39.1)	84.79% (-19.60%, 98.07%)

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]	2020/10-2021/3	Unvaccinated	10 (90.9)	336 (60.3)	346 (60.9)	67.33% (-152.43%, 95.77%)
		Total	11 (100.0)	557 (100.0)	568 (100.0)	
		Vaccinated	1 (4.8)	30 (13.3)	31 (12.6)	
		Unvaccinated	20 (95.2)	196 (86.7)	216 (87.4)	NA*
		Total	21 (100.0)	226 (100.0)	247 (100.0)	
		Vaccinated	0	395 (31.8)	395 (31.6)	
	2021/10-2022/4	Unvaccinated	8 (100.0)	846 (68.2)	854 (68.4)	90.57% (28.05%, 98.76%)
		Total	8 (100.0)	1241 (100.0)	1249 (100.0)	
		Vaccinated	1 (6.7)	552 (43.1)	553 (42.7)	
	2022/10-2023/4	Unvaccinated	14 (93.3)	729 (56.9)	743 (57.3)	NA*
		Total	15 (100.0)	1281 (100.0)	1296 (100.0)	
Vaccinated		0	488 (39.8)	488 (39.5)		
2024/10-2025/4	Unvaccinated	8 (100.0)	739 (60.2)	747 (60.5)	89.27% (55.19%, 97.43%)	
	Total	8 (100.0)	1227 (100.0)	1235 (100.0)		
	Vaccinated	2 (5.7)	860 (36.1)	862 (35.7)		
Gender	Male	Unvaccinated	33 (94.3)	1522 (63.9)	1555 (64.3)	NA*
		Total	35 (100.0)	2382 (100.0)	2417 (100.0)	
		Vaccinated	0	605 (38.0)	605 (37.6)	
	Female	Unvaccinated	17 (100.0)	988 (62.0)	1005 (62.4)	NA*

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types				Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total				17 (100.0)	1593 (100.0)	1610 (100.0)	
G3	Age of onset group	<=11 months	Vaccinated	2 (8.0)	520 (35.1)	522 (34.7)	83.93% (31.57%, 96.23%)
			Unvaccinated	23 (92.0)	961 (64.9)	984 (65.3)	
			Total	25 (100.0)	1481 (100.0)	1506 (100.0)	
		12-23 months	Vaccinated	4 (4.9)	655 (39.5)	659 (37.9)	92.05% (78.18%, 97.11%)
			Unvaccinated	77 (95.1)	1002 (60.5)	1079 (62.1)	
			Total	81 (100.0)	1657 (100.0)	1738 (100.0)	
		24-35 months	Vaccinated	2 (4.8)	182 (37.4)	184 (34.8)	91.65% (65.03%, 98.01%)
			Unvaccinated	40 (95.2)	304 (62.6)	344 (65.2)	
			Total	42 (100.0)	486 (100.0)	528 (100.0)	
		>=36 months	Vaccinated	3 (3.2)	108 (30.8)	111 (24.9)	92.58% (76.05%, 97.70%)
			Unvaccinated	91 (96.8)	243 (69.2)	334 (75.1)	
			Total	94 (100.0)	351 (100.0)	445 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	6 (4.2)	870 (37.6)	876 (35.6)	92.78% (83.59%, 96.83%)
			Unvaccinated	138 (95.8)	1444 (62.4)	1582 (64.4)	
			Total	144 (100.0)	2314 (100.0)	2458 (100.0)	
		Non-RV peak season	Vaccinated	5 (5.1)	595 (35.8)	600 (34.1)	90.37% (76.18%, 96.10%)
			Unvaccinated	93 (94.9)	1066 (64.2)	1159 (65.9)	
			Total	98 (100.0)	1661 (100.0)	1759 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Vaccinated	5 (3.6)	1030 (39.5)	1035 (37.7)	94.20% (85.79%, 97.63%)
		Unvaccinated	132 (96.4)	1577 (60.5)	1709 (62.3)	
		Total	137 (100.0)	2607 (100.0)	2744 (100.0)	
	Rural	Vaccinated	6 (5.8)	434 (31.7)	440 (29.9)	86.70% (69.42%, 94.21%)
		Unvaccinated	97 (94.2)	933 (68.3)	1030 (70.1)	
		Total	103 (100.0)	1367 (100.0)	1470 (100.0)	
Regions of study hospitals ^[2]	East	Vaccinated	4 (2.6)	752 (38.0)	756 (35.5)	95.55% (87.95%, 98.36%)
		Unvaccinated	147 (97.4)	1228 (62.0)	1375 (64.5)	
		Total	151 (100.0)	1980 (100.0)	2131 (100.0)	
	Central	Vaccinated	3 (5.8)	338 (34.3)	341 (32.9)	88.28% (62.12%, 96.37%)
		Unvaccinated	49 (94.2)	647 (65.7)	696 (67.1)	
		Total	52 (100.0)	985 (100.0)	1037 (100.0)	
	West	Vaccinated	4 (10.3)	375 (37.1)	379 (36.1)	80.65% (45.12%, 93.18%)
		Unvaccinated	35 (89.7)	635 (62.9)	670 (63.9)	
		Total	39 (100.0)	1010 (100.0)	1049 (100.0)	
Clinical setting	Inpatient	Vaccinated	8 (3.5)	1244 (36.4)	1252 (34.3)	93.64% (87.09%, 96.87%)
		Unvaccinated	220 (96.5)	2174 (63.6)	2394 (65.7)	
		Total	228 (100.0)	3418 (100.0)	3646 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]	Outpatient	Vaccinated	3 (21.4)	221 (39.7)	224 (39.2)	58.53% (-50.31%, 88.56%)
		Unvaccinated	11 (78.6)	336 (60.3)	347 (60.8)	
		Total	14 (100.0)	557 (100.0)	571 (100.0)	
	2020/10-2021/3	Vaccinated	0	30 (13.3)	30 (13.2)	NA*
		Unvaccinated	1 (100.0)	196 (86.7)	197 (86.8)	
		Total	1 (100.0)	226 (100.0)	227 (100.0)	
	2021/10-2022/4	Vaccinated	1 (16.7)	395 (31.8)	396 (31.8)	57.16% (-267.87%, 95.01%)
		Unvaccinated	5 (83.3)	846 (68.2)	851 (68.2)	
		Total	6 (100.0)	1241 (100.0)	1247 (100.0)	
	2022/10-2023/4	Vaccinated	2 (15.4)	552 (43.1)	554 (42.8)	75.99% (-8.77%, 94.70%)
		Unvaccinated	11 (84.6)	729 (56.9)	740 (57.2)	
		Total	13 (100.0)	1281 (100.0)	1294 (100.0)	
	2024/10-2025/4	Vaccinated	8 (3.6)	488 (39.8)	496 (34.2)	94.34% (88.43%, 97.23%)
		Unvaccinated	214 (96.4)	739 (60.2)	953 (65.8)	
		Total	222 (100.0)	1227 (100.0)	1449 (100.0)	
Gender	Male	Vaccinated	5 (3.3)	860 (36.1)	865 (34.1)	93.98% (85.26%, 97.54%)
		Unvaccinated	147 (96.7)	1522 (63.9)	1669 (65.9)	
		Total	152 (100.0)	2382 (100.0)	2534 (100.0)	
	Female	Vaccinated	6 (6.7)	605 (38.0)	611 (36.3)	88.33% (73.12%, 94.93%)

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types				Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
G8	Age of onset group	<=11 months	Unvaccinated	84 (93.3)	988 (62.0)	1072 (63.7)	
			Total	90 (100.0)	1593 (100.0)	1683 (100.0)	
	Age of onset group	<=11 months	Vaccinated	13 (13.3)	520 (35.1)	533 (33.8)	71.74% (48.84%, 84.38%)
			Unvaccinated	85 (86.7)	961 (64.9)	1046 (66.2)	
			Total	98 (100.0)	1481 (100.0)	1579 (100.0)	
		12-23 months	Vaccinated	29 (10.7)	655 (39.5)	684 (35.5)	81.59% (72.60%, 87.63%)
			Unvaccinated	241 (89.3)	1002 (60.5)	1243 (64.5)	
			Total	270 (100.0)	1657 (100.0)	1927 (100.0)	
		24-35 months	Vaccinated	14 (11.7)	182 (37.4)	196 (32.3)	77.94% (60.33%, 87.73%)
			Unvaccinated	106 (88.3)	304 (62.6)	410 (67.7)	
			Total	120 (100.0)	486 (100.0)	606 (100.0)	
		>=36 months	Vaccinated	6 (6.0)	108 (30.8)	114 (25.3)	85.64% (66.20%, 93.90%)
			Unvaccinated	94 (94.0)	243 (69.2)	337 (74.7)	
			Total	100 (100.0)	351 (100.0)	451 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	36 (10.3)	870 (37.6)	906 (34.0)	80.91% (72.77%, 86.62%)
			Unvaccinated	313 (89.7)	1444 (62.4)	1757 (66.0)	
			Total	349 (100.0)	2314 (100.0)	2663 (100.0)	
	Birth seasons	Non-RV peak season	Vaccinated	26 (10.9)	595 (35.8)	621 (32.7)	78.13% (66.74%, 85.62%)
			Unvaccinated	213 (89.1)	1066 (64.2)	1279 (67.3)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			239 (100.0)	1661 (100.0)	1900 (100.0)	
Residence location	Urban	Vaccinated	42 (11.8)	1030 (39.5)	1072 (36.2)	79.46% (71.38%, 85.25%)
		Unvaccinated	313 (88.2)	1577 (60.5)	1890 (63.8)	
		Total	355 (100.0)	2607 (100.0)	2962 (100.0)	
	Rural	Vaccinated	20 (8.6)	434 (31.7)	454 (28.4)	79.81% (67.63%, 87.41%)
		Unvaccinated	213 (91.4)	933 (68.3)	1146 (71.6)	
		Total	233 (100.0)	1367 (100.0)	1600 (100.0)	
Regions of study hospitals ^[2]	East	Vaccinated	33 (12.2)	752 (38.0)	785 (34.9)	77.26% (66.91%, 84.38%)
		Unvaccinated	237 (87.8)	1228 (62.0)	1465 (65.1)	
		Total	270 (100.0)	1980 (100.0)	2250 (100.0)	
	Central	Vaccinated	9 (5.1)	338 (34.3)	347 (29.9)	89.74% (79.68%, 94.82%)
		Unvaccinated	168 (94.9)	647 (65.7)	815 (70.1)	
		Total	177 (100.0)	985 (100.0)	1162 (100.0)	
	West	Vaccinated	20 (14.2)	375 (37.1)	395 (34.3)	72.01% (54.31%, 82.85%)
		Unvaccinated	121 (85.8)	635 (62.9)	756 (65.7)	
		Total	141 (100.0)	1010 (100.0)	1151 (100.0)	
Clinical setting	Inpatient	Vaccinated	56 (10.3)	1244 (36.4)	1300 (32.8)	79.95% (73.33%, 84.92%)
		Unvaccinated	488 (89.7)	2174 (63.6)	2662 (67.2)	
		Total	544 (100.0)	3418 (100.0)	3962 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]	Outpatient	Vaccinated	6 (13.6)	221 (39.7)	227 (37.8)	75.99% (42.26%, 90.02%)
		Unvaccinated	38 (86.4)	336 (60.3)	374 (62.2)	
		Total	44 (100.0)	557 (100.0)	601 (100.0)	
	2020/10-2021/3	Vaccinated	1 (5.6)	30 (13.3)	31 (12.7)	61.55% (-199.46%, 95.06%)
		Unvaccinated	17 (94.4)	196 (86.7)	213 (87.3)	
		Total	18 (100.0)	226 (100.0)	244 (100.0)	
	2021/10-2022/4	Vaccinated	31 (9.1)	395 (31.8)	426 (27.0)	78.44% (68.22%, 85.38%)
		Unvaccinated	308 (90.9)	846 (68.2)	1154 (73.0)	
		Total	339 (100.0)	1241 (100.0)	1580 (100.0)	
	2022/10-2023/4	Vaccinated	20 (17.1)	552 (43.1)	572 (40.9)	72.77% (55.38%, 83.38%)
		Unvaccinated	97 (82.9)	729 (56.9)	826 (59.1)	
		Total	117 (100.0)	1281 (100.0)	1398 (100.0)	
Gender	2024/10-2025/4	Vaccinated	10 (8.8)	488 (39.8)	498 (37.1)	85.44% (71.86%, 92.46%)
		Unvaccinated	104 (91.2)	739 (60.2)	843 (62.9)	
		Total	114 (100.0)	1227 (100.0)	1341 (100.0)	
	Male	Vaccinated	37 (10.0)	860 (36.1)	897 (32.6)	80.34% (72.10%, 86.14%)
		Unvaccinated	333 (90.0)	1522 (63.9)	1855 (67.4)	
		Total	370 (100.0)	2382 (100.0)	2752 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)	
G9	Female	Vaccinated	25 (11.5)	605 (38.0)	630 (34.8)	78.85% (67.52%, 86.22%)	
		Unvaccinated	193 (88.5)	988 (62.0)	1181 (65.2)		
		Total	218 (100.0)	1593 (100.0)	1811 (100.0)		
	Age of onset group	<=11 months	Vaccinated	6 (4.6)	520 (35.1)	526 (32.6)	91.13% (79.74%, 96.12%)
			Unvaccinated	125 (95.4)	961 (64.9)	1086 (67.4)	
			Total	131 (100.0)	1481 (100.0)	1612 (100.0)	
		12-23 months	Vaccinated	17 (4.5)	655 (39.5)	672 (33.0)	92.86% (88.27%, 95.65%)
			Unvaccinated	364 (95.5)	1002 (60.5)	1366 (67.0)	
			Total	381 (100.0)	1657 (100.0)	2038 (100.0)	
		24-35 months	Vaccinated	7 (7.0)	182 (37.4)	189 (32.3)	87.43% (72.30%, 94.29%)
			Unvaccinated	93 (93.0)	304 (62.6)	397 (67.7)	
			Total	100 (100.0)	486 (100.0)	586 (100.0)	
>=36 months		Vaccinated	6 (10.9)	108 (30.8)	114 (28.1)	72.45% (33.74%, 88.54%)	
		Unvaccinated	49 (89.1)	243 (69.2)	292 (71.9)		
		Total	55 (100.0)	351 (100.0)	406 (100.0)		
Birth seasons	RV peak season ^[1]	Vaccinated	21 (5.3)	870 (37.6)	891 (32.9)	90.71% (85.46%, 94.06%)	
		Unvaccinated	375 (94.7)	1444 (62.4)	1819 (67.1)		
		Total	396 (100.0)	2314 (100.0)	2710 (100.0)		
	Non-RV peak season	Vaccinated	15 (5.5)	595 (35.8)	610 (31.6)	89.50% (82.15%, 93.82%)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Unvaccinated	256 (94.5)	1066 (64.2)	1322 (68.4)	90.55% (85.63%, 93.79%)
		Total	271 (100.0)	1661 (100.0)	1932 (100.0)	
		Vaccinated	24 (5.8)	1030 (39.5)	1054 (34.9)	
	Rural	Unvaccinated	389 (94.2)	1577 (60.5)	1966 (65.1)	90.23% (81.93%, 94.72%)
		Total	413 (100.0)	2607 (100.0)	3020 (100.0)	
		Vaccinated	11 (4.3)	434 (31.7)	445 (27.5)	
Regions of study hospitals ^[2]	East	Unvaccinated	242 (95.7)	933 (68.3)	1175 (72.5)	86.32% (77.03%, 91.85%)
		Total	253 (100.0)	1367 (100.0)	1620 (100.0)	
		Vaccinated	11 (4.3)	434 (31.7)	445 (27.5)	
	Central	Unvaccinated	16 (7.7)	752 (38.0)	768 (35.1)	94.15% (84.06%, 97.86%)
		Total	191 (92.3)	1228 (62.0)	1419 (64.9)	
		Vaccinated	207 (100.0)	1980 (100.0)	2187 (100.0)	
	West	Unvaccinated	4 (3.0)	338 (34.3)	342 (30.5)	91.23% (85.27%, 94.78%)
		Total	131 (97.0)	647 (65.7)	778 (69.5)	
		Vaccinated	135 (100.0)	985 (100.0)	1120 (100.0)	
Clinical setting	Inpatient	Unvaccinated	16 (4.9)	375 (37.1)	391 (29.3)	91.29% (87.11%, 94.12%)
		Total	309 (95.1)	635 (62.9)	944 (70.7)	
		Vaccinated	325 (100.0)	1010 (100.0)	1335 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			569 (100.0)	3418 (100.0)	3987 (100.0)	
Symptom onset seasons ^[3]	Outpatient	Vaccinated	9 (9.2)	221 (39.7)	230 (35.1)	84.63% (68.84%, 92.41%)
		Unvaccinated	89 (90.8)	336 (60.3)	425 (64.9)	
		Total	98 (100.0)	557 (100.0)	655 (100.0)	
	2020/10-2021/3	Vaccinated	6 (1.7)	30 (13.3)	36 (6.2)	88.70% (72.38%, 95.38%)
		Unvaccinated	347 (98.3)	196 (86.7)	543 (93.8)	
		Total	353 (100.0)	226 (100.0)	579 (100.0)	
	2021/10-2022/4	Vaccinated	18 (14.8)	395 (31.8)	413 (30.3)	62.93% (37.99%, 77.83%)
		Unvaccinated	104 (85.2)	846 (68.2)	950 (69.7)	
		Total	122 (100.0)	1241 (100.0)	1363 (100.0)	
	2022/10-2023/4	Vaccinated	4 (5.7)	552 (43.1)	556 (41.2)	92.00% (77.91%, 97.10%)
		Unvaccinated	66 (94.3)	729 (56.9)	795 (58.8)	
		Total	70 (100.0)	1281 (100.0)	1351 (100.0)	
	2024/10-2025/4	Vaccinated	8 (6.6)	488 (39.8)	496 (36.8)	89.37% (78.03%, 94.85%)
		Unvaccinated	114 (93.4)	739 (60.2)	853 (63.2)	
		Total	122 (100.0)	1227 (100.0)	1349 (100.0)	
Gender	Male	Vaccinated	21 (5.2)	860 (36.1)	881 (31.6)	90.37% (84.94%, 93.84%)
		Unvaccinated	386 (94.8)	1522 (63.9)	1908 (68.4)	
		Total	407 (100.0)	2382 (100.0)	2789 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.1. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G-type (Analysis Population)
(Continued)

<i>Types</i>			<i>Case Group</i>	<i>Control Group</i>	<i>Total</i>	<i>VE</i>
			<i>(RV +)</i>	<i>(RV -)</i>		
			<i>N (%)</i>	<i>N (%)</i>	<i>N (%)</i>	<i>(%, 95% CI)</i>
Female	Vaccinated		15 (5.8)	605 (38.0)	620 (33.5)	89.99% (82.99%, 94.12%)
	Unvaccinated		245 (94.2)	988 (62.0)	1233 (66.5)	
	Total		260 (100.0)	1593 (100.0)	1853 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
P[4]	Age of onset group	<=11 months	Vaccinated	0	520 (35.1)	NA*
			Unvaccinated	15 (100.0)	961 (64.9)	
			Total	15 (100.0)	1481 (100.0)	
		12-23 months	Vaccinated	4 (12.5)	655 (39.5)	78.15% (37.41%, 92.37%)
			Unvaccinated	28 (87.5)	1002 (60.5)	
			Total	32 (100.0)	1657 (100.0)	
		24-35 months	Vaccinated	0	182 (37.4)	NA*
			Unvaccinated	9 (100.0)	304 (62.6)	
			Total	9 (100.0)	486 (100.0)	
		>=36 months	Vaccinated	0	108 (30.8)	NA*
			Unvaccinated	7 (100.0)	243 (69.2)	
			Total	7 (100.0)	351 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	3 (10.3)	870 (37.6)	80.85% (36.54%, 94.22%)
			Unvaccinated	26 (89.7)	1444 (62.4)	
			Total	29 (100.0)	2314 (100.0)	
		Non-RV peak season	Vaccinated	1 (2.9)	595 (35.8)	94.57% (60.20%, 99.26%)
			Unvaccinated	33 (97.1)	1066 (64.2)	
			Total	34 (100.0)	1661 (100.0)	
	Residence location	Urban	Vaccinated	4 (10.5)	1030 (39.5)	81.99% (49.09%, 93.63%)

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Regions of study hospitals ^[2]	Rural	Unvaccinated	34 (89.5)	1577 (60.5)	1611 (60.9)	NA*
		Total	38 (100.0)	2607 (100.0)	2645 (100.0)	
		Vaccinated	0	434 (31.7)	434 (31.2)	
		Unvaccinated	25 (100.0)	933 (68.3)	958 (68.8)	80.79% (16.61%, 95.57%)
		Total	25 (100.0)	1367 (100.0)	1392 (100.0)	
		Vaccinated	2 (10.5)	752 (38.0)	754 (37.7)	
	East	Unvaccinated	17 (89.5)	1228 (62.0)	1245 (62.3)	86.32% (-4.42%, 98.21%)
		Total	19 (100.0)	1980 (100.0)	1999 (100.0)	
		Vaccinated	1 (6.7)	338 (34.3)	339 (33.9)	
		Unvaccinated	14 (93.3)	647 (65.7)	661 (66.1)	93.95% (55.37%, 99.18%)
		Total	15 (100.0)	985 (100.0)	1000 (100.0)	
		Vaccinated	1 (3.4)	375 (37.1)	376 (36.2)	
Central	Unvaccinated	28 (96.6)	635 (62.9)	663 (63.8)	89.30% (65.60%, 96.67%)	
	Total	29 (100.0)	1010 (100.0)	1039 (100.0)		
	Vaccinated	3 (5.8)	1244 (36.4)	1247 (35.9)		
Clinical setting	West	Unvaccinated	49 (94.2)	2174 (63.6)	2223 (64.1)	84.79% (-19.60%, 98.07%)
		Total	52 (100.0)	3418 (100.0)	3470 (100.0)	
		Vaccinated	1 (9.1)	221 (39.7)	222 (39.1)	
	Inpatient	Unvaccinated	10 (90.9)	336 (60.3)	346 (60.9)	
		Total				
		Vaccinated				

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			11 (100.0)	557 (100.0)	568 (100.0)	
Symptom onset seasons ^[3]	2020/10-2021/3	Vaccinated	2 (8.7)	30 (13.3)	32 (12.9)	37.78% (-178.98%, 86.12%)
		Unvaccinated	21 (91.3)	196 (86.7)	217 (87.1)	
		Total	23 (100.0)	226 (100.0)	249 (100.0)	
	2021/10-2022/4	Vaccinated	0	395 (31.8)	395 (31.6)	NA*
		Unvaccinated	9 (100.0)	846 (68.2)	855 (68.4)	
		Total	9 (100.0)	1241 (100.0)	1250 (100.0)	
	2022/10-2023/4	Vaccinated	2 (8.0)	552 (43.1)	554 (42.4)	88.51% (51.08%, 97.30%)
		Unvaccinated	23 (92.0)	729 (56.9)	752 (57.6)	
		Total	25 (100.0)	1281 (100.0)	1306 (100.0)	
	2024/10-2025/4	Vaccinated	0	488 (39.8)	488 (39.6)	NA*
		Unvaccinated	6 (100.0)	739 (60.2)	745 (60.4)	
		Total	6 (100.0)	1227 (100.0)	1233 (100.0)	
Gender	Male	Vaccinated	4 (10.0)	860 (36.1)	864 (35.7)	80.34% (44.57%, 93.02%)
		Unvaccinated	36 (90.0)	1522 (63.9)	1558 (64.3)	
		Total	40 (100.0)	2382 (100.0)	2422 (100.0)	
	Female	Vaccinated	0	605 (38.0)	605 (37.4)	NA*
		Unvaccinated	23 (100.0)	988 (62.0)	1011 (62.6)	
		Total	23 (100.0)	1593 (100.0)	1616 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)
(Continued)

Types				Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
P[8]	Age of onset group	<=11 months	Vaccinated	21 (8.0)	520 (35.1)	541 (31.0)	83.90% (74.53%, 89.82%)
			Unvaccinated	241 (92.0)	961 (64.9)	1202 (69.0)	
			Total	262 (100.0)	1481 (100.0)	1743 (100.0)	
		12-23 months	Vaccinated	51 (6.8)	655 (39.5)	706 (29.4)	88.81% (84.88%, 91.71%)
			Unvaccinated	697 (93.2)	1002 (60.5)	1699 (70.6)	
			Total	748 (100.0)	1657 (100.0)	2405 (100.0)	
		24-35 months	Vaccinated	23 (8.9)	182 (37.4)	205 (27.5)	83.72% (74.06%, 89.78%)
			Unvaccinated	236 (91.1)	304 (62.6)	540 (72.5)	
			Total	259 (100.0)	486 (100.0)	745 (100.0)	
		>=36 months	Vaccinated	14 (5.7)	108 (30.8)	122 (20.4)	86.48% (75.73%, 92.47%)
			Unvaccinated	233 (94.3)	243 (69.2)	476 (79.6)	
			Total	247 (100.0)	351 (100.0)	598 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	62 (6.9)	870 (37.6)	932 (29.0)	87.69% (83.85%, 90.62%)
			Unvaccinated	836 (93.1)	1444 (62.4)	2280 (71.0)	
			Total	898 (100.0)	2314 (100.0)	3212 (100.0)	
		Non-RV peak season	Vaccinated	47 (7.6)	595 (35.8)	642 (28.2)	85.25% (79.82%, 89.23%)
			Unvaccinated	571 (92.4)	1066 (64.2)	1637 (71.8)	
			Total	618 (100.0)	1661 (100.0)	2279 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Vaccinated	70 (7.6)	1030 (39.5)	1100 (31.2)	87.35% (83.65%, 90.20%)
		Unvaccinated	847 (92.4)	1577 (60.5)	2424 (68.8)	
		Total	917 (100.0)	2607 (100.0)	3524 (100.0)	
	Rural	Vaccinated	38 (6.4)	434 (31.7)	472 (24.0)	85.36% (79.27%, 89.66%)
		Unvaccinated	558 (93.6)	933 (68.3)	1491 (76.0)	
		Total	596 (100.0)	1367 (100.0)	1963 (100.0)	
Regions of study hospitals ^[2]	East	Vaccinated	50 (7.9)	752 (38.0)	802 (30.7)	85.99% (81.04%, 89.65%)
		Unvaccinated	583 (92.1)	1228 (62.0)	1811 (69.3)	
		Total	633 (100.0)	1980 (100.0)	2613 (100.0)	
	Central	Vaccinated	16 (4.3)	338 (34.3)	354 (26.1)	91.34% (85.47%, 94.84%)
		Unvaccinated	354 (95.7)	647 (65.7)	1001 (73.9)	
		Total	370 (100.0)	985 (100.0)	1355 (100.0)	
	West	Vaccinated	43 (8.4)	375 (37.1)	418 (27.4)	84.51% (78.29%, 88.94%)
		Unvaccinated	470 (91.6)	635 (62.9)	1105 (72.6)	
		Total	513 (100.0)	1010 (100.0)	1523 (100.0)	
Clinical setting	Inpatient	Vaccinated	91 (6.7)	1244 (36.4)	1335 (28.0)	87.42% (84.26%, 89.94%)
		Unvaccinated	1264 (93.3)	2174 (63.6)	3438 (72.0)	
		Total	1355 (100.0)	3418 (100.0)	4773 (100.0)	
	Outpatient	Vaccinated	18 (11.2)	221 (39.7)	239 (33.3)	80.86% (67.85%, 88.61%)

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)
(Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]		Unvaccinated	143 (88.8)	336 (60.3)	479 (66.7)	
		Total	161 (100.0)	557 (100.0)	718 (100.0)	
	2020/10-2021/3	Vaccinated	6 (1.6)	30 (13.3)	36 (6.0)	89.46% (74.25%, 95.69%)
		Unvaccinated	372 (98.4)	196 (86.7)	568 (94.0)	
		Total	378 (100.0)	226 (100.0)	604 (100.0)	
	2021/10-2022/4	Vaccinated	50 (10.5)	395 (31.8)	445 (25.9)	74.80% (65.41%, 81.63%)
		Unvaccinated	425 (89.5)	846 (68.2)	1271 (74.1)	
		Total	475 (100.0)	1241 (100.0)	1716 (100.0)	
	2022/10-2023/4	Vaccinated	26 (13.3)	552 (43.1)	578 (39.2)	79.68% (68.85%, 86.75%)
		Unvaccinated	169 (86.7)	729 (56.9)	898 (60.8)	
		Total	195 (100.0)	1281 (100.0)	1476 (100.0)	
	2024/10-2025/4	Vaccinated	27 (5.8)	488 (39.8)	515 (30.4)	90.73% (86.10%, 93.82%)
		Unvaccinated	441 (94.2)	739 (60.2)	1180 (69.6)	
		Total	468 (100.0)	1227 (100.0)	1695 (100.0)	
Gender	Male	Vaccinated	62 (6.6)	860 (36.1)	922 (27.7)	87.53% (83.65%, 90.49%)
		Unvaccinated	880 (93.4)	1522 (63.9)	2402 (72.3)	
		Total	942 (100.0)	2382 (100.0)	3324 (100.0)	
	Female	Vaccinated	47 (8.2)	605 (38.0)	652 (30.1)	85.44% (80.04%, 89.37%)
		Unvaccinated	527 (91.8)	988 (62.0)	1515 (69.9)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to P-type (Analysis Population)
(Continued)

<i>Types</i>	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Total	574 (100.0)	1593 (100.0)	2167 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
G1P[8]	Age of onset group	<=11 months	Vaccinated	0	520 (35.1)	NA*
			Unvaccinated	4 (100.0)	961 (64.9)	
			Total	4 (100.0)	1481 (100.0)	
		12-23 months	Vaccinated	1 (11.1)	655 (39.5)	80.88% (-53.24%, 97.61%)
			Unvaccinated	8 (88.9)	1002 (60.5)	
			Total	9 (100.0)	1657 (100.0)	
		24-35 months	Vaccinated	0	182 (37.4)	NA*
			Unvaccinated	2 (100.0)	304 (62.6)	
			Total	2 (100.0)	486 (100.0)	
		>=36 months	Vaccinated	0	108 (30.8)	NA*
			Unvaccinated	2 (100.0)	243 (69.2)	
			Total	2 (100.0)	351 (100.0)	
Birth seasons	RV peak season ^[1]	Vaccinated	1 (11.1)	870 (37.6)	79.25% (-66.16%, 97.41%)	
		Unvaccinated	8 (88.9)	1444 (62.4)		
		Total	9 (100.0)	2314 (100.0)		
	Non-RV peak season	Vaccinated	0	595 (35.8)	NA*	
		Unvaccinated	8 (100.0)	1066 (64.2)		
		Total	8 (100.0)	1661 (100.0)		
Residence location	Urban	Vaccinated	0	1030 (39.5)	NA*	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Regions of study hospitals ^[2]	Rural	Unvaccinated	6 (100.0)	1577 (60.5)	1583 (60.6)	78.50% (-68.46%, 97.26%)
		Total	6 (100.0)	2607 (100.0)	2613 (100.0)	
		Vaccinated	1 (9.1)	434 (31.7)	435 (31.6)	
	East	Unvaccinated	10 (90.9)	933 (68.3)	943 (68.4)	NA*
		Total	11 (100.0)	1367 (100.0)	1378 (100.0)	
		Vaccinated	0	752 (38.0)	752 (37.8)	
	Central	Unvaccinated	9 (100.0)	1228 (62.0)	1237 (62.2)	NA*
		Total	9 (100.0)	1980 (100.0)	1989 (100.0)	
		Vaccinated	0	338 (34.3)	338 (34.1)	
	West	Unvaccinated	5 (100.0)	647 (65.7)	652 (65.9)	15.33% (-836.89%, 92.35%)
		Total	5 (100.0)	985 (100.0)	990 (100.0)	
		Vaccinated	1 (33.3)	375 (37.1)	376 (37.1)	
Clinical setting	Inpatient	Unvaccinated	2 (66.7)	635 (62.9)	637 (62.9)	87.51% (4.96%, 98.36%)
		Total	3 (100.0)	1010 (100.0)	1013 (100.0)	
		Vaccinated	1 (6.7)	1244 (36.4)	1245 (36.3)	
	Outpatient	Unvaccinated	14 (93.3)	2174 (63.6)	2188 (63.7)	NA*
		Total	15 (100.0)	3418 (100.0)	3433 (100.0)	
		Vaccinated	0	221 (39.7)	221 (39.5)	
		Unvaccinated	2 (100.0)	336 (60.3)	338 (60.5)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			2 (100.0)	557 (100.0)	559 (100.0)	
Symptom onset seasons ^[3]	2020/10-2021/3	Vaccinated	0	30 (13.3)	30 (13.3)	NA*
		Unvaccinated	0	196 (86.7)	196 (86.7)	
		Total	0	226 (100.0)	226 (100.0)	
	2021/10-2022/4	Vaccinated	0	395 (31.8)	395 (31.7)	NA*
		Unvaccinated	6 (100.0)	846 (68.2)	852 (68.3)	
		Total	6 (100.0)	1241 (100.0)	1247 (100.0)	
	2022/10-2023/4	Vaccinated	0	552 (43.1)	552 (42.9)	NA*
		Unvaccinated	5 (100.0)	729 (56.9)	734 (57.1)	
		Total	5 (100.0)	1281 (100.0)	1286 (100.0)	
	2024/10-2025/4	Vaccinated	1 (16.7)	488 (39.8)	489 (39.7)	69.71% (-160.03%, 96.47%)
		Unvaccinated	5 (83.3)	739 (60.2)	744 (60.3)	
		Total	6 (100.0)	1227 (100.0)	1233 (100.0)	
Gender	Male	Vaccinated	1 (7.1)	860 (36.1)	861 (35.9)	86.38% (-4.25%, 98.22%)
		Unvaccinated	13 (92.9)	1522 (63.9)	1535 (64.1)	
		Total	14 (100.0)	2382 (100.0)	2396 (100.0)	
	Female	Vaccinated	0	605 (38.0)	605 (37.9)	NA*
		Unvaccinated	3 (100.0)	988 (62.0)	991 (62.1)	
		Total	3 (100.0)	1593 (100.0)	1596 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)	
G2P[4]	Age of onset group	<=11 months	Vaccinated	0	520 (35.1)	NA*	
			Unvaccinated	13 (100.0)	961 (64.9)		
			Total	13 (100.0)	1481 (100.0)		
		12-23 months	Vaccinated	2 (6.9)	655 (39.5)	657 (39.0)	88.67% (52.19%, 97.31%)
			Unvaccinated	27 (93.1)	1002 (60.5)	1029 (61.0)	
			Total	29 (100.0)	1657 (100.0)	1686 (100.0)	
		24-35 months	Vaccinated	0	182 (37.4)	182 (37.1)	NA*
			Unvaccinated	5 (100.0)	304 (62.6)	309 (62.9)	
			Total	5 (100.0)	486 (100.0)	491 (100.0)	
		>=36 months	Vaccinated	0	108 (30.8)	108 (30.6)	NA*
			Unvaccinated	2 (100.0)	243 (69.2)	245 (69.4)	
			Total	2 (100.0)	351 (100.0)	353 (100.0)	
Birth seasons	RV peak season ^[1]	Vaccinated	2 (8.7)	870 (37.6)	872 (37.3)	84.19% (32.42%, 96.30%)	
		Unvaccinated	21 (91.3)	1444 (62.4)	1465 (62.7)		
		Total	23 (100.0)	2314 (100.0)	2337 (100.0)		
	Non-RV peak season	Vaccinated	0	595 (35.8)	595 (35.3)	NA*	
		Unvaccinated	26 (100.0)	1066 (64.2)	1092 (64.7)		
		Total	26 (100.0)	1661 (100.0)	1687 (100.0)		

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Vaccinated	2 (7.1)	1030 (39.5)	1032 (39.2)	88.21% (50.26%, 97.21%)
		Unvaccinated	26 (92.9)	1577 (60.5)	1603 (60.8)	
		Total	28 (100.0)	2607 (100.0)	2635 (100.0)	
	Rural	Vaccinated	0	434 (31.7)	434 (31.3)	NA*
		Unvaccinated	21 (100.0)	933 (68.3)	954 (68.7)	
		Total	21 (100.0)	1367 (100.0)	1388 (100.0)	
Regions of study hospitals [2]	East	Vaccinated	0	752 (38.0)	752 (37.8)	NA*
		Unvaccinated	8 (100.0)	1228 (62.0)	1236 (62.2)	
		Total	8 (100.0)	1980 (100.0)	1988 (100.0)	
	Central	Vaccinated	1 (6.7)	338 (34.3)	339 (33.9)	86.32% (-4.42%, 98.21%)
		Unvaccinated	14 (93.3)	647 (65.7)	661 (66.1)	
		Total	15 (100.0)	985 (100.0)	1000 (100.0)	
	West	Vaccinated	1 (3.8)	375 (37.1)	376 (36.3)	93.23% (49.81%, 99.09%)
		Unvaccinated	25 (96.2)	635 (62.9)	660 (63.7)	
		Total	26 (100.0)	1010 (100.0)	1036 (100.0)	
Clinical setting	Inpatient	Vaccinated	1 (2.6)	1244 (36.4)	1245 (36.0)	95.40% (66.46%, 99.37%)
		Unvaccinated	38 (97.4)	2174 (63.6)	2212 (64.0)	
		Total	39 (100.0)	3418 (100.0)	3457 (100.0)	
	Outpatient	Vaccinated	1 (10.0)	221 (39.7)	222 (39.2)	83.11% (-34.27%, 97.87%)
		Unvaccinated				
		Total				

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

[1] October to April of the following year.

[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]	2020/10-2021/3	Unvaccinated	9 (90.0)	336 (60.3)	345 (60.8)	65.61% (-166.38%, 95.56%)
		Total	10 (100.0)	557 (100.0)	567 (100.0)	
		Vaccinated	1 (5.0)	30 (13.3)	31 (12.6)	
		Unvaccinated	19 (95.0)	196 (86.7)	215 (87.4)	
		Total	20 (100.0)	226 (100.0)	246 (100.0)	
	2021/10-2022/4	Vaccinated	0	395 (31.8)	395 (31.6)	NA*
		Unvaccinated	8 (100.0)	846 (68.2)	854 (68.4)	
		Total	8 (100.0)	1241 (100.0)	1249 (100.0)	
	2022/10-2023/4	Vaccinated	1 (6.7)	552 (43.1)	553 (42.7)	90.57% (28.05%, 98.76%)
		Unvaccinated	14 (93.3)	729 (56.9)	743 (57.3)	
		Total	15 (100.0)	1281 (100.0)	1296 (100.0)	
	2024/10-2025/4	Vaccinated	0	488 (39.8)	488 (39.6)	NA*
		Unvaccinated	6 (100.0)	739 (60.2)	745 (60.4)	
		Total	6 (100.0)	1227 (100.0)	1233 (100.0)	
Gender	Male	Vaccinated	2 (5.9)	860 (36.1)	862 (35.7)	88.94% (53.73%, 97.36%)
		Unvaccinated	32 (94.1)	1522 (63.9)	1554 (64.3)	
		Total	34 (100.0)	2382 (100.0)	2416 (100.0)	
	Female	Vaccinated	0	605 (38.0)	605 (37.6)	NA*
		Unvaccinated	15 (100.0)	988 (62.0)	1003 (62.4)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types				Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total				15 (100.0)	1593 (100.0)	1608 (100.0)	
G3P[8]	Age of onset group	<=11 months	Vaccinated	2 (8.0)	520 (35.1)	522 (34.7)	83.93% (31.57%, 96.23%)
			Unvaccinated	23 (92.0)	961 (64.9)	984 (65.3)	
			Total	25 (100.0)	1481 (100.0)	1506 (100.0)	
	12-23 months		Vaccinated	4 (5.0)	655 (39.5)	659 (37.9)	91.95% (77.89%, 97.07%)
			Unvaccinated	76 (95.0)	1002 (60.5)	1078 (62.1)	
			Total	80 (100.0)	1657 (100.0)	1737 (100.0)	
	24-35 months		Vaccinated	2 (5.1)	182 (37.4)	184 (35.0)	90.97% (62.09%, 97.85%)
			Unvaccinated	37 (94.9)	304 (62.6)	341 (65.0)	
			Total	39 (100.0)	486 (100.0)	525 (100.0)	
	>=36 months		Vaccinated	3 (3.3)	108 (30.8)	111 (25.1)	92.42% (75.50%, 97.65%)
			Unvaccinated	89 (96.7)	243 (69.2)	332 (74.9)	
			Total	92 (100.0)	351 (100.0)	443 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	6 (4.2)	870 (37.6)	876 (35.7)	92.73% (83.47%, 96.80%)
			Unvaccinated	137 (95.8)	1444 (62.4)	1581 (64.3)	
			Total	143 (100.0)	2314 (100.0)	2457 (100.0)	
	Non-RV peak season		Vaccinated	5 (5.4)	595 (35.8)	600 (34.2)	89.82% (74.80%, 95.89%)
			Unvaccinated	88 (94.6)	1066 (64.2)	1154 (65.8)	
			Total	93 (100.0)	1661 (100.0)	1754 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Vaccinated	5 (3.7)	1030 (39.5)	1035 (37.7)	94.11% (85.56%, 97.60%)
		Unvaccinated	130 (96.3)	1577 (60.5)	1707 (62.3)	
		Total	135 (100.0)	2607 (100.0)	2742 (100.0)	
	Rural	Vaccinated	6 (6.1)	434 (31.7)	440 (30.0)	86.13% (68.08%, 93.97%)
		Unvaccinated	93 (93.9)	933 (68.3)	1026 (70.0)	
		Total	99 (100.0)	1367 (100.0)	1466 (100.0)	
Regions of study hospitals ^[2]	East	Vaccinated	4 (2.7)	752 (38.0)	756 (35.5)	95.43% (87.61%, 98.31%)
		Unvaccinated	143 (97.3)	1228 (62.0)	1371 (64.5)	
		Total	147 (100.0)	1980 (100.0)	2127 (100.0)	
	Central	Vaccinated	3 (5.9)	338 (34.3)	341 (32.9)	88.03% (61.29%, 96.30%)
		Unvaccinated	48 (94.1)	647 (65.7)	695 (67.1)	
		Total	51 (100.0)	985 (100.0)	1036 (100.0)	
	West	Vaccinated	4 (10.5)	375 (37.1)	379 (36.2)	80.08% (43.42%, 92.99%)
		Unvaccinated	34 (89.5)	635 (62.9)	669 (63.8)	
		Total	38 (100.0)	1010 (100.0)	1048 (100.0)	
Clinical setting	Inpatient	Vaccinated	8 (3.6)	1244 (36.4)	1252 (34.4)	93.47% (86.72%, 96.79%)
		Unvaccinated	214 (96.4)	2174 (63.6)	2388 (65.6)	
		Total	222 (100.0)	3418 (100.0)	3640 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]	Outpatient	Vaccinated	3 (21.4)	221 (39.7)	224 (39.2)	58.53% (-50.31%, 88.56%)
		Unvaccinated	11 (78.6)	336 (60.3)	347 (60.8)	
		Total	14 (100.0)	557 (100.0)	571 (100.0)	
	2020/10-2021/3	Vaccinated	0	30 (13.3)	30 (13.2)	NA*
		Unvaccinated	1 (100.0)	196 (86.7)	197 (86.8)	
		Total	1 (100.0)	226 (100.0)	227 (100.0)	
	2021/10-2022/4	Vaccinated	1 (33.3)	395 (31.8)	396 (31.8)	-7.09% (-1084.51%, 90.32%)
		Unvaccinated	2 (66.7)	846 (68.2)	848 (68.2)	
		Total	3 (100.0)	1241 (100.0)	1244 (100.0)	
	2022/10-2023/4	Vaccinated	2 (16.7)	552 (43.1)	554 (42.8)	73.59% (-21.03%, 94.24%)
		Unvaccinated	10 (83.3)	729 (56.9)	739 (57.2)	
		Total	12 (100.0)	1281 (100.0)	1293 (100.0)	
	2024/10-2025/4	Vaccinated	8 (3.6)	488 (39.8)	496 (34.3)	94.29% (88.32%, 97.20%)
		Unvaccinated	212 (96.4)	739 (60.2)	951 (65.7)	
		Total	220 (100.0)	1227 (100.0)	1447 (100.0)	
Gender	Male	Vaccinated	5 (3.4)	860 (36.1)	865 (34.2)	93.77% (84.74%, 97.46%)
		Unvaccinated	142 (96.6)	1522 (63.9)	1664 (65.8)	
		Total	147 (100.0)	2382 (100.0)	2529 (100.0)	
	Female	Vaccinated	6 (6.7)	605 (38.0)	611 (36.3)	88.19% (72.79%, 94.87%)

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
G8P[8]	Age of onset group	<=11 months	Unvaccinated	83 (93.3)	988 (62.0)	71.74% (48.84%, 84.38%)
			Total	89 (100.0)	1593 (100.0)	
		12-23 months	Vaccinated	13 (13.3)	520 (35.1)	81.52% (72.49%, 87.58%)
			Unvaccinated	85 (86.7)	961 (64.9)	
			Total	98 (100.0)	1481 (100.0)	
		24-35 months	Vaccinated	29 (10.8)	655 (39.5)	77.73% (59.94%, 87.62%)
			Unvaccinated	240 (89.2)	304 (62.6)	
			Total	269 (100.0)	486 (100.0)	
		>=36 months	Vaccinated	14 (11.8)	182 (37.4)	88.03% (69.74%, 95.27%)
			Unvaccinated	105 (88.2)	243 (69.2)	
			Total	119 (100.0)	351 (100.0)	
	Birth seasons	RV peak season ^[1]	Vaccinated	5 (5.1)	108 (30.8)	81.38% (73.33%, 87.00%)
			Unvaccinated	94 (94.9)	1444 (62.4)	
			Total	99 (100.0)	2314 (100.0)	
		Non-RV peak season	Vaccinated	35 (10.1)	870 (37.6)	78.03% (66.58%, 85.55%)
Unvaccinated			312 (89.9)	1066 (64.2)		
Total			347 (100.0)	1278 (67.3)		

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			238 (100.0)	1661 (100.0)	1899 (100.0)	
Residence location	Urban	Vaccinated	41 (11.6)	1030 (39.5)	1071 (36.2)	79.94% (71.97%, 85.65%)
		Unvaccinated	313 (88.4)	1577 (60.5)	1890 (63.8)	
		Total	354 (100.0)	2607 (100.0)	2961 (100.0)	
	Rural	Vaccinated	20 (8.7)	434 (31.7)	454 (28.4)	79.62% (67.32%, 87.30%)
		Unvaccinated	211 (91.3)	933 (68.3)	1144 (71.6)	
		Total	231 (100.0)	1367 (100.0)	1598 (100.0)	
Regions of study hospitals ^[2]	East	Vaccinated	32 (11.9)	752 (38.0)	784 (34.9)	77.95% (67.75%, 84.92%)
		Unvaccinated	237 (88.1)	1228 (62.0)	1465 (65.1)	
		Total	269 (100.0)	1980 (100.0)	2249 (100.0)	
	Central	Vaccinated	9 (5.1)	338 (34.3)	347 (29.9)	89.61% (79.43%, 94.76%)
		Unvaccinated	166 (94.9)	647 (65.7)	813 (70.1)	
		Total	175 (100.0)	985 (100.0)	1160 (100.0)	
	West	Vaccinated	20 (14.2)	375 (37.1)	395 (34.3)	72.01% (54.31%, 82.85%)
		Unvaccinated	121 (85.8)	635 (62.9)	756 (65.7)	
		Total	141 (100.0)	1010 (100.0)	1151 (100.0)	
Clinical setting	Inpatient	Vaccinated	55 (10.2)	1244 (36.4)	1299 (32.8)	80.22% (73.64%, 85.16%)
		Unvaccinated	486 (89.8)	2174 (63.6)	2660 (67.2)	
		Total	541 (100.0)	3418 (100.0)	3959 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Symptom onset seasons ^[3]	Outpatient	Vaccinated	6 (13.6)	221 (39.7)	227 (37.8)	75.99% (42.26%, 90.02%)
		Unvaccinated	38 (86.4)	336 (60.3)	374 (62.2)	
		Total	44 (100.0)	557 (100.0)	601 (100.0)	
	2020/10-2021/3	Vaccinated	1 (5.6)	30 (13.3)	31 (12.7)	61.55% (-199.46%, 95.06%)
		Unvaccinated	17 (94.4)	196 (86.7)	213 (87.3)	
		Total	18 (100.0)	226 (100.0)	244 (100.0)	
	2021/10-2022/4	Vaccinated	30 (8.9)	395 (31.8)	425 (26.9)	79.07% (68.98%, 85.88%)
		Unvaccinated	307 (91.1)	846 (68.2)	1153 (73.1)	
		Total	337 (100.0)	1241 (100.0)	1578 (100.0)	
	2022/10-2023/4	Vaccinated	20 (17.1)	552 (43.1)	572 (40.9)	72.77% (55.38%, 83.38%)
		Unvaccinated	97 (82.9)	729 (56.9)	826 (59.1)	
		Total	117 (100.0)	1281 (100.0)	1398 (100.0)	
Gender	2024/10-2025/4	Vaccinated	10 (8.8)	488 (39.8)	498 (37.2)	85.30% (71.58%, 92.39%)
		Unvaccinated	103 (91.2)	739 (60.2)	842 (62.8)	
		Total	113 (100.0)	1227 (100.0)	1340 (100.0)	
	Male	Vaccinated	36 (9.8)	860 (36.1)	896 (32.6)	80.81% (72.66%, 86.53%)
		Unvaccinated	332 (90.2)	1522 (63.9)	1854 (67.4)	
		Total	368 (100.0)	2382 (100.0)	2750 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)	
G9P[8]	Female	Vaccinated	25 (11.5)	605 (38.0)	630 (34.8)	78.74% (67.35%, 86.15%)	
		Unvaccinated	192 (88.5)	988 (62.0)	1180 (65.2)		
		Total	217 (100.0)	1593 (100.0)	1810 (100.0)		
	Age of onset group	<=11 months	Vaccinated	6 (4.6)	520 (35.1)	526 (32.7)	91.06% (79.57%, 96.09%)
			Unvaccinated	124 (95.4)	961 (64.9)	1085 (67.3)	
			Total	130 (100.0)	1481 (100.0)	1611 (100.0)	
		12-23 months	Vaccinated	15 (4.0)	655 (39.5)	670 (33.0)	93.64% (89.25%, 96.24%)
			Unvaccinated	361 (96.0)	1002 (60.5)	1363 (67.0)	
			Total	376 (100.0)	1657 (100.0)	2033 (100.0)	
		24-35 months	Vaccinated	7 (7.2)	182 (37.4)	189 (32.4)	87.01% (71.35%, 94.11%)
			Unvaccinated	90 (92.8)	304 (62.6)	394 (67.6)	
			Total	97 (100.0)	486 (100.0)	583 (100.0)	
		>=36 months	Vaccinated	6 (12.0)	108 (30.8)	114 (28.4)	69.30% (25.82%, 87.30%)
			Unvaccinated	44 (88.0)	243 (69.2)	287 (71.6)	
			Total	50 (100.0)	351 (100.0)	401 (100.0)	
Birth seasons	RV peak season ^[1]	Vaccinated	19 (4.9)	870 (37.6)	889 (32.9)	91.50% (86.42%, 94.68%)	
		Unvaccinated	371 (95.1)	1444 (62.4)	1815 (67.1)		
		Total	390 (100.0)	2314 (100.0)	2704 (100.0)		
	Non-RV peak season	Vaccinated	15 (5.7)	595 (35.8)	610 (31.7)	89.16% (81.57%, 93.62%)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Residence location	Urban	Unvaccinated	248 (94.3)	1066 (64.2)	1314 (68.3)	91.16% (86.32%, 94.29%)
		Total	263 (100.0)	1661 (100.0)	1924 (100.0)	
		Vaccinated	22 (5.5)	1030 (39.5)	1052 (35.0)	
	Rural	Unvaccinated	381 (94.5)	1577 (60.5)	1958 (65.0)	90.06% (81.62%, 94.63%)
		Total	403 (100.0)	2607 (100.0)	3010 (100.0)	
		Vaccinated	11 (4.4)	434 (31.7)	445 (27.5)	
Regions of study hospitals ^[2]	East	Unvaccinated	238 (95.6)	933 (68.3)	1171 (72.5)	87.44% (78.20%, 92.76%)
		Total	249 (100.0)	1367 (100.0)	1616 (100.0)	
		Vaccinated	14 (7.1)	752 (38.0)	766 (35.2)	
	Central	Unvaccinated	182 (92.9)	1228 (62.0)	1410 (64.8)	94.11% (83.93%, 97.84%)
		Total	196 (100.0)	1980 (100.0)	2176 (100.0)	
		Vaccinated	4 (3.0)	338 (34.3)	342 (30.6)	
	West	Unvaccinated	130 (97.0)	647 (65.7)	777 (69.4)	91.17% (85.17%, 94.74%)
		Total	134 (100.0)	985 (100.0)	1119 (100.0)	
		Vaccinated	16 (5.0)	375 (37.1)	391 (29.3)	
	Clinical setting	Unvaccinated	307 (95.0)	635 (62.9)	942 (70.7)	91.76% (87.61%, 94.51%)
		Total	323 (100.0)	1010 (100.0)	1333 (100.0)	
		Vaccinated	25 (4.5)	1244 (36.4)	1269 (31.9)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

Types			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Total			555 (100.0)	3418 (100.0)	3973 (100.0)	
Symptom onset seasons ^[3]	Outpatient	Vaccinated	9 (9.2)	221 (39.7)	230 (35.1)	84.63% (68.84%, 92.41%)
		Unvaccinated	89 (90.8)	336 (60.3)	425 (64.9)	
		Total	98 (100.0)	557 (100.0)	655 (100.0)	
	2020/10-2021/3	Vaccinated	5 (1.4)	30 (13.3)	35 (6.1)	90.53% (75.20%, 96.38%)
		Unvaccinated	345 (98.6)	196 (86.7)	541 (93.9)	
		Total	350 (100.0)	226 (100.0)	576 (100.0)	
	2021/10-2022/4	Vaccinated	18 (14.8)	395 (31.8)	413 (30.3)	62.93% (37.99%, 77.83%)
		Unvaccinated	104 (85.2)	846 (68.2)	950 (69.7)	
		Total	122 (100.0)	1241 (100.0)	1363 (100.0)	
	2022/10-2023/4	Vaccinated	3 (5.0)	552 (43.1)	555 (41.4)	93.05% (77.69%, 97.83%)
		Unvaccinated	57 (95.0)	729 (56.9)	786 (58.6)	
		Total	60 (100.0)	1281 (100.0)	1341 (100.0)	
	2024/10-2025/4	Vaccinated	8 (6.6)	488 (39.8)	496 (36.8)	89.27% (77.83%, 94.81%)
		Unvaccinated	113 (93.4)	739 (60.2)	852 (63.2)	
		Total	121 (100.0)	1227 (100.0)	1348 (100.0)	
Gender	Male	Vaccinated	19 (4.7)	860 (36.1)	879 (31.6)	91.22% (85.98%, 94.50%)
		Unvaccinated	383 (95.3)	1522 (63.9)	1905 (68.4)	
		Total	402 (100.0)	2382 (100.0)	2784 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.2.3. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G/P type combinations (Analysis Population) (Continued)

<i>Types</i>			<i>Case Group</i> <i>(RV +)</i>	<i>Control Group</i> <i>(RV -)</i>	<i>Total</i>	<i>VE</i>
			<i>N (%)</i>	<i>N (%)</i>	<i>N (%)</i>	<i>(%, 95% CI)</i>
Female	Vaccinated		15 (6.0)	605 (38.0)	620 (33.6)	89.61% (82.33%, 93.90%)
	Unvaccinated		236 (94.0)	988 (62.0)	1224 (66.4)	
	Total		251 (100.0)	1593 (100.0)	1844 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

* NA=Not Applicable: No patient with ELISA positive results in the vaccinated or unvaccinated group.

Table 14.4.3.1. G1-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	17 (0)	3975 (0)	3992 (0)
	Mean (Std)	21.06 (13.785)	17.88 (12.099)	17.89 (12.106)
	Median	16.80	14.40	14.40
	Q1, Q3	12.80, 23.90	9.50, 21.80	9.55, 21.80
	Min, Max	7.1, 53.0	3.7, 77.4	3.7, 77.4
	<=11 months	4 (23.5)	1481 (37.3)	1485 (37.2)
	12-23 months	9 (52.9)	1657 (41.7)	1666 (41.7)
	24-35 months	2 (11.8)	486 (12.2)	488 (12.2)
	>=36 months	2 (11.8)	351 (8.8)	353 (8.8)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	9 (52.9)	2314 (58.2)	2323 (58.2)
	Non-RV peak season	8 (47.1)	1661 (41.8)	1669 (41.8)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Residence location (n, %)	Urban	6 (35.3)	2607 (65.6)	2613 (65.5)
	Rural	11 (64.7)	1367 (34.4)	1378 (34.5)
	Missing	0	1 (0.0)	1 (0.0)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Regions of study hospitals (n, %) ^[2]	East	9 (52.9)	1980 (49.8)	1989 (49.8)
	Central	5 (29.4)	985 (24.8)	990 (24.8)
	West	3 (17.6)	1010 (25.4)	1013 (25.4)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Clinical settings (n, %)	Inpatient	15 (88.2)	3418 (86.0)	3433 (86.0)
	Outpatient	2 (11.8)	557 (14.0)	559 (14.0)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.1. G1-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	0	226 (5.7)	226 (5.7)
	2021/10-2022/4	6 (35.3)	1241 (31.2)	1247 (31.2)
	2022/10-2023/4	5 (29.4)	1281 (32.2)	1286 (32.2)
	2024/10-2025/4	6 (35.3)	1227 (30.9)	1233 (30.9)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Gender (n, %)	Male	14 (82.4)	2382 (59.9)	2396 (60.0)
	Female	3 (17.6)	1593 (40.1)	1596 (40.0)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
College and above for either parent's education level (n, %)	No	8 (47.1)	1072 (27.0)	1080 (27.1)
	Yes	9 (52.9)	2643 (66.5)	2652 (66.4)
	Missing	0	260 (6.5)	260 (6.5)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.2. G2-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	52 (0)	3975 (0)	4027 (0)
	Mean (Std)	17.45 (9.041)	17.88 (12.099)	17.87 (12.063)
	Median	16.20	14.40	14.40
	Q1, Q3	11.25, 20.55	9.50, 21.80	9.60, 21.80
	Min, Max	4.3, 51.6	3.7, 77.4	3.7, 77.4
	<=11 months	14 (26.9)	1481 (37.3)	1495 (37.1)
	12-23 months	31 (59.6)	1657 (41.7)	1688 (41.9)
	24-35 months	5 (9.6)	486 (12.2)	491 (12.2)
	>=36 months	2 (3.8)	351 (8.8)	353 (8.8)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	24 (46.2)	2314 (58.2)	2338 (58.1)
	Non-RV peak season	28 (53.8)	1661 (41.8)	1689 (41.9)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)
Residence location (n, %)	Urban	28 (53.8)	2607 (65.6)	2635 (65.4)
	Rural	24 (46.2)	1367 (34.4)	1391 (34.5)
	Missing	0	1 (0.0)	1 (0.0)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)
Regions of study hospitals (n, %) ^[2]	East	9 (17.3)	1980 (49.8)	1989 (49.4)
	Central	16 (30.8)	985 (24.8)	1001 (24.9)
	West	27 (51.9)	1010 (25.4)	1037 (25.8)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)
Clinical settings (n, %)	Inpatient	41 (78.8)	3418 (86.0)	3459 (85.9)
	Outpatient	11 (21.2)	557 (14.0)	568 (14.1)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.2. G2-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	21 (40.4)	226 (5.7)	247 (6.1)
	2021/10-2022/4	8 (15.4)	1241 (31.2)	1249 (31.0)
	2022/10-2023/4	15 (28.8)	1281 (32.2)	1296 (32.2)
	2024/10-2025/4	8 (15.4)	1227 (30.9)	1235 (30.7)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)
Gender (n, %)	Male	35 (67.3)	2382 (59.9)	2417 (60.0)
	Female	17 (32.7)	1593 (40.1)	1610 (40.0)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)
College and above for either parent's education level (n, %)	No	12 (23.1)	1072 (27.0)	1084 (26.9)
	Yes	19 (36.5)	2643 (66.5)	2662 (66.1)
	Missing	21 (40.4)	260 (6.5)	281 (7.0)
	Total	52 (100.0)	3975 (100.0)	4027 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.3. G3-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	242 (0)	3975 (0)	4217 (0)
	Mean (Std)	32.48 (18.800)	17.88 (12.099)	18.72 (13.028)
	Median	26.50	14.40	14.80
	Q1, Q3	16.40, 45.70	9.50, 21.80	9.70, 22.90
	Min, Max	5.1, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	25 (10.3)	1481 (37.3)	1506 (35.7)
	12-23 months	81 (33.5)	1657 (41.7)	1738 (41.2)
	24-35 months	42 (17.4)	486 (12.2)	528 (12.5)
	>=36 months	94 (38.8)	351 (8.8)	445 (10.6)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	144 (59.5)	2314 (58.2)	2458 (58.3)
	Non-RV peak season	98 (40.5)	1661 (41.8)	1759 (41.7)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)
Residence location (n, %)	Urban	137 (56.6)	2607 (65.6)	2744 (65.1)
	Rural	103 (42.6)	1367 (34.4)	1470 (34.9)
	Missing	2 (0.8)	1 (0.0)	3 (0.1)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)
Regions of study hospitals (n, %) ^[2]	East	151 (62.4)	1980 (49.8)	2131 (50.5)
	Central	52 (21.5)	985 (24.8)	1037 (24.6)
	West	39 (16.1)	1010 (25.4)	1049 (24.9)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)
Clinical settings (n, %)	Inpatient	228 (94.2)	3418 (86.0)	3646 (86.5)
	Outpatient	14 (5.8)	557 (14.0)	571 (13.5)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.3. G3-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	1 (0.4)	226 (5.7)	227 (5.4)
	2021/10-2022/4	6 (2.5)	1241 (31.2)	1247 (29.6)
	2022/10-2023/4	13 (5.4)	1281 (32.2)	1294 (30.7)
	2024/10-2025/4	222 (91.7)	1227 (30.9)	1449 (34.4)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)
Gender (n, %)	Male	152 (62.8)	2382 (59.9)	2534 (60.1)
	Female	90 (37.2)	1593 (40.1)	1683 (39.9)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)
College and above for either parent's education level (n, %)	No	87 (36.0)	1072 (27.0)	1159 (27.5)
	Yes	151 (62.4)	2643 (66.5)	2794 (66.3)
	Missing	4 (1.7)	260 (6.5)	264 (6.3)
	Total	242 (100.0)	3975 (100.0)	4217 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.4. G8-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	588 (0)	3975 (0)	4563 (0)
	Mean (Std)	23.93 (14.061)	17.88 (12.099)	18.66 (12.532)
	Median	20.50	14.40	15.10
	Q1, Q3	14.45, 29.55	9.50, 21.80	10.00, 23.00
	Min, Max	3.8, 77.9	3.7, 77.4	3.7, 77.9
	<=11 months	98 (16.7)	1481 (37.3)	1579 (34.6)
	12-23 months	270 (45.9)	1657 (41.7)	1927 (42.2)
	24-35 months	120 (20.4)	486 (12.2)	606 (13.3)
	>=36 months	100 (17.0)	351 (8.8)	451 (9.9)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	349 (59.4)	2314 (58.2)	2663 (58.4)
	Non-RV peak season	239 (40.6)	1661 (41.8)	1900 (41.6)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)
Residence location (n, %)	Urban	355 (60.4)	2607 (65.6)	2962 (64.9)
	Rural	233 (39.6)	1367 (34.4)	1600 (35.1)
	Missing	0	1 (0.0)	1 (0.0)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)
Regions of study hospitals (n, %) ^[2]	East	270 (45.9)	1980 (49.8)	2250 (49.3)
	Central	177 (30.1)	985 (24.8)	1162 (25.5)
	West	141 (24.0)	1010 (25.4)	1151 (25.2)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)
Clinical settings (n, %)	Inpatient	544 (92.5)	3418 (86.0)	3962 (86.8)
	Outpatient	44 (7.5)	557 (14.0)	601 (13.2)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.4. G8-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	18 (3.1)	226 (5.7)	244 (5.3)
	2021/10-2022/4	339 (57.7)	1241 (31.2)	1580 (34.6)
	2022/10-2023/4	117 (19.9)	1281 (32.2)	1398 (30.6)
	2024/10-2025/4	114 (19.4)	1227 (30.9)	1341 (29.4)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)
Gender (n, %)	Male	370 (62.9)	2382 (59.9)	2752 (60.3)
	Female	218 (37.1)	1593 (40.1)	1811 (39.7)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)
College and above for either parent's education level (n, %)	No	213 (36.2)	1072 (27.0)	1285 (28.2)
	Yes	349 (59.4)	2643 (66.5)	2992 (65.6)
	Missing	26 (4.4)	260 (6.5)	286 (6.3)
	Total	588 (100.0)	3975 (100.0)	4563 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

[1] October to April of the following year.

[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.5. G9-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	667 (0)	3975 (0)	4642 (0)
	Mean (Std)	19.94 (10.940)	17.88 (12.099)	18.18 (11.960)
	Median	17.70	14.40	14.90
	Q1, Q3	13.00, 23.50	9.50, 21.80	10.00, 22.20
	Min, Max	4.1, 75.1	3.7, 77.4	3.7, 77.4
	<=11 months	131 (19.6)	1481 (37.3)	1612 (34.7)
	12-23 months	381 (57.1)	1657 (41.7)	2038 (43.9)
	24-35 months	100 (15.0)	486 (12.2)	586 (12.6)
	>=36 months	55 (8.2)	351 (8.8)	406 (8.7)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	396 (59.4)	2314 (58.2)	2710 (58.4)
	Non-RV peak season	271 (40.6)	1661 (41.8)	1932 (41.6)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)
Residence location (n, %)	Urban	413 (61.9)	2607 (65.6)	3020 (65.1)
	Rural	253 (37.9)	1367 (34.4)	1620 (34.9)
	Missing	1 (0.1)	1 (0.0)	2 (0.0)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)
Regions of study hospitals (n, %) ^[2]	East	207 (31.0)	1980 (49.8)	2187 (47.1)
	Central	135 (20.2)	985 (24.8)	1120 (24.1)
	West	325 (48.7)	1010 (25.4)	1335 (28.8)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)
Clinical settings (n, %)	Inpatient	569 (85.3)	3418 (86.0)	3987 (85.9)
	Outpatient	98 (14.7)	557 (14.0)	655 (14.1)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.5. G9-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	353 (52.9)	226 (5.7)	579 (12.5)
	2021/10-2022/4	122 (18.3)	1241 (31.2)	1363 (29.4)
	2022/10-2023/4	70 (10.5)	1281 (32.2)	1351 (29.1)
	2024/10-2025/4	122 (18.3)	1227 (30.9)	1349 (29.1)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)
Gender (n, %)	Male	407 (61.0)	2382 (59.9)	2789 (60.1)
	Female	260 (39.0)	1593 (40.1)	1853 (39.9)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)
College and above for either parent's education level (n, %)	No	94 (14.1)	1072 (27.0)	1166 (25.1)
	Yes	219 (32.8)	2643 (66.5)	2862 (61.7)
	Missing	354 (53.1)	260 (6.5)	614 (13.2)
	Total	667 (100.0)	3975 (100.0)	4642 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.6. P[4]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	63 (0)	3975 (0)	4038 (0)
	Mean (Std)	19.87 (11.266)	17.88 (12.099)	17.91 (12.087)
	Median	16.80	14.40	14.50
	Q1, Q3	12.50, 25.40	9.50, 21.80	9.60, 21.90
	Min, Max	4.3, 51.6	3.7, 77.4	3.7, 77.4
	<=11 months	15 (23.8)	1481 (37.3)	1496 (37.0)
	12-23 months	32 (50.8)	1657 (41.7)	1689 (41.8)
	24-35 months	9 (14.3)	486 (12.2)	495 (12.3)
	>=36 months	7 (11.1)	351 (8.8)	358 (8.9)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	29 (46.0)	2314 (58.2)	2343 (58.0)
	Non-RV peak season	34 (54.0)	1661 (41.8)	1695 (42.0)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)
Residence location (n, %)	Urban	38 (60.3)	2607 (65.6)	2645 (65.5)
	Rural	25 (39.7)	1367 (34.4)	1392 (34.5)
	Missing	0	1 (0.0)	1 (0.0)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)
Regions of study hospitals (n, %) ^[2]	East	19 (30.2)	1980 (49.8)	1999 (49.5)
	Central	15 (23.8)	985 (24.8)	1000 (24.8)
	West	29 (46.0)	1010 (25.4)	1039 (25.7)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)
Clinical settings (n, %)	Inpatient	52 (82.5)	3418 (86.0)	3470 (85.9)
	Outpatient	11 (17.5)	557 (14.0)	568 (14.1)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.6. P[4]-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	23 (36.5)	226 (5.7)	249 (6.2)
	2021/10-2022/4	9 (14.3)	1241 (31.2)	1250 (31.0)
	2022/10-2023/4	25 (39.7)	1281 (32.2)	1306 (32.3)
	2024/10-2025/4	6 (9.5)	1227 (30.9)	1233 (30.5)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)
Gender (n, %)	Male	40 (63.5)	2382 (59.9)	2422 (60.0)
	Female	23 (36.5)	1593 (40.1)	1616 (40.0)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)
College and above for either parent's education level (n, %)	No	12 (19.0)	1072 (27.0)	1084 (26.8)
	Yes	28 (44.4)	2643 (66.5)	2671 (66.1)
	Missing	23 (36.5)	260 (6.5)	283 (7.0)
	Total	63 (100.0)	3975 (100.0)	4038 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.7. P[8]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	1516 (0)	3975 (0)	5491 (0)
	Mean (Std)	23.41 (14.445)	17.88 (12.099)	19.41 (13.025)
	Median	19.40	14.40	15.70
	Q1, Q3	14.00, 28.25	9.50, 21.80	10.50, 23.70
	Min, Max	3.8, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	262 (17.3)	1481 (37.3)	1743 (31.7)
	12-23 months	748 (49.3)	1657 (41.7)	2405 (43.8)
	24-35 months	259 (17.1)	486 (12.2)	745 (13.6)
	>=36 months	247 (16.3)	351 (8.8)	598 (10.9)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	898 (59.2)	2314 (58.2)	3212 (58.5)
	Non-RV peak season	618 (40.8)	1661 (41.8)	2279 (41.5)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)
Residence location (n, %)	Urban	917 (60.5)	2607 (65.6)	3524 (64.2)
	Rural	596 (39.3)	1367 (34.4)	1963 (35.7)
	Missing	3 (0.2)	1 (0.0)	4 (0.1)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)
Regions of study hospitals (n, %) ^[2]	East	633 (41.8)	1980 (49.8)	2613 (47.6)
	Central	370 (24.4)	985 (24.8)	1355 (24.7)
	West	513 (33.8)	1010 (25.4)	1523 (27.7)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)
Clinical settings (n, %)	Inpatient	1355 (89.4)	3418 (86.0)	4773 (86.9)
	Outpatient	161 (10.6)	557 (14.0)	718 (13.1)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.7. P[8]-Descriptive analysis (Analysis Population) (Continued)

		<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	378 (24.9)	226 (5.7)	604 (11.0)
	2021/10-2022/4	475 (31.3)	1241 (31.2)	1716 (31.3)
	2022/10-2023/4	195 (12.9)	1281 (32.2)	1476 (26.9)
	2024/10-2025/4	468 (30.9)	1227 (30.9)	1695 (30.9)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)
Gender (n, %)	Male	942 (62.1)	2382 (59.9)	3324 (60.5)
	Female	574 (37.9)	1593 (40.1)	2167 (39.5)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)
College and above for either parent's education level (n, %)	No	404 (26.6)	1072 (27.0)	1476 (26.9)
	Yes	722 (47.6)	2643 (66.5)	3365 (61.3)
	Missing	390 (25.7)	260 (6.5)	650 (11.8)
	Total	1516 (100.0)	3975 (100.0)	5491 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.8. G1P[8]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	17 (0)	3975 (0)	3992 (0)
	Mean (Std)	21.06 (13.785)	17.88 (12.099)	17.89 (12.106)
	Median	16.80	14.40	14.40
	Q1, Q3	12.80, 23.90	9.50, 21.80	9.55, 21.80
	Min, Max	7.1, 53.0	3.7, 77.4	3.7, 77.4
	<=11 months	4 (23.5)	1481 (37.3)	1485 (37.2)
	12-23 months	9 (52.9)	1657 (41.7)	1666 (41.7)
	24-35 months	2 (11.8)	486 (12.2)	488 (12.2)
	>=36 months	2 (11.8)	351 (8.8)	353 (8.8)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	9 (52.9)	2314 (58.2)	2323 (58.2)
	Non-RV peak season	8 (47.1)	1661 (41.8)	1669 (41.8)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Residence location (n, %)	Urban	6 (35.3)	2607 (65.6)	2613 (65.5)
	Rural	11 (64.7)	1367 (34.4)	1378 (34.5)
	Missing	0	1 (0.0)	1 (0.0)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Regions of study hospitals (n, %) ^[2]	East	9 (52.9)	1980 (49.8)	1989 (49.8)
	Central	5 (29.4)	985 (24.8)	990 (24.8)
	West	3 (17.6)	1010 (25.4)	1013 (25.4)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Clinical settings (n, %)	Inpatient	15 (88.2)	3418 (86.0)	3433 (86.0)
	Outpatient	2 (11.8)	557 (14.0)	559 (14.0)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.8. G2P[4]-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	0	226 (5.7)	226 (5.7)
	2021/10-2022/4	6 (35.3)	1241 (31.2)	1247 (31.2)
	2022/10-2023/4	5 (29.4)	1281 (32.2)	1286 (32.2)
	2024/10-2025/4	6 (35.3)	1227 (30.9)	1233 (30.9)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
Gender (n, %)	Male	14 (82.4)	2382 (59.9)	2396 (60.0)
	Female	3 (17.6)	1593 (40.1)	1596 (40.0)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)
College and above for either parent's education level (n, %)	No	8 (47.1)	1072 (27.0)	1080 (27.1)
	Yes	9 (52.9)	2643 (66.5)	2652 (66.4)
	Missing	0	260 (6.5)	260 (6.5)
	Total	17 (100.0)	3975 (100.0)	3992 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.9. G2P[4]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	49 (0)	3975 (0)	4024 (0)
	Mean (Std)	17.57 (9.250)	17.88 (12.099)	17.87 (12.067)
	Median	15.70	14.40	14.40
	Q1, Q3	11.30, 21.10	9.50, 21.80	9.60, 21.80
	Min, Max	4.3, 51.6	3.7, 77.4	3.7, 77.4
	<=11 months	13 (26.5)	1481 (37.3)	1494 (37.1)
	12-23 months	29 (59.2)	1657 (41.7)	1686 (41.9)
	24-35 months	5 (10.2)	486 (12.2)	491 (12.2)
	>=36 months	2 (4.1)	351 (8.8)	353 (8.8)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	23 (46.9)	2314 (58.2)	2337 (58.1)
	Non-RV peak season	26 (53.1)	1661 (41.8)	1687 (41.9)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)
Residence location (n, %)	Urban	28 (57.1)	2607 (65.6)	2635 (65.5)
	Rural	21 (42.9)	1367 (34.4)	1388 (34.5)
	Missing	0	1 (0.0)	1 (0.0)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)
Regions of study hospitals (n, %) ^[2]	East	8 (16.3)	1980 (49.8)	1988 (49.4)
	Central	15 (30.6)	985 (24.8)	1000 (24.9)
	West	26 (53.1)	1010 (25.4)	1036 (25.7)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)
Clinical settings (n, %)	Inpatient	39 (79.6)	3418 (86.0)	3457 (85.9)
	Outpatient	10 (20.4)	557 (14.0)	567 (14.1)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.9. G2P[4]-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	20 (40.8)	226 (5.7)	246 (6.1)
	2021/10-2022/4	8 (16.3)	1241 (31.2)	1249 (31.0)
	2022/10-2023/4	15 (30.6)	1281 (32.2)	1296 (32.2)
	2024/10-2025/4	6 (12.2)	1227 (30.9)	1233 (30.6)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)
Gender (n, %)	Male	34 (69.4)	2382 (59.9)	2416 (60.0)
	Female	15 (30.6)	1593 (40.1)	1608 (40.0)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)
College and above for either parent's education level (n, %)	No	10 (20.4)	1072 (27.0)	1082 (26.9)
	Yes	19 (38.8)	2643 (66.5)	2662 (66.2)
	Missing	20 (40.8)	260 (6.5)	280 (7.0)
	Total	49 (100.0)	3975 (100.0)	4024 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.10. G3P[8]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	236 (0)	3975 (0)	4211 (0)
	Mean (Std)	32.43 (18.882)	17.88 (12.099)	18.69 (13.011)
	Median	26.50	14.40	14.80
	Q1, Q3	16.40, 45.90	9.50, 21.80	9.70, 22.90
	Min, Max	5.1, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	25 (10.6)	1481 (37.3)	1506 (35.8)
	12-23 months	80 (33.9)	1657 (41.7)	1737 (41.2)
	24-35 months	39 (16.5)	486 (12.2)	525 (12.5)
	>=36 months	92 (39.0)	351 (8.8)	443 (10.5)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	143 (60.6)	2314 (58.2)	2457 (58.3)
	Non-RV peak season	93 (39.4)	1661 (41.8)	1754 (41.7)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)
Residence location (n, %)	Urban	135 (57.2)	2607 (65.6)	2742 (65.1)
	Rural	99 (41.9)	1367 (34.4)	1466 (34.8)
	Missing	2 (0.8)	1 (0.0)	3 (0.1)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)
Regions of study hospitals (n, %) ^[2]	East	147 (62.3)	1980 (49.8)	2127 (50.5)
	Central	51 (21.6)	985 (24.8)	1036 (24.6)
	West	38 (16.1)	1010 (25.4)	1048 (24.9)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)
Clinical settings (n, %)	Inpatient	222 (94.1)	3418 (86.0)	3640 (86.4)
	Outpatient	14 (5.9)	557 (14.0)	571 (13.6)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.10. G3P[8]-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	1 (0.4)	226 (5.7)	227 (5.4)
	2021/10-2022/4	3 (1.3)	1241 (31.2)	1244 (29.5)
	2022/10-2023/4	12 (5.1)	1281 (32.2)	1293 (30.7)
	2024/10-2025/4	220 (93.2)	1227 (30.9)	1447 (34.4)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)
Gender (n, %)	Male	147 (62.3)	2382 (59.9)	2529 (60.1)
	Female	89 (37.7)	1593 (40.1)	1682 (39.9)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)
College and above for either parent's education level (n, %)	No	84 (35.6)	1072 (27.0)	1156 (27.5)
	Yes	148 (62.7)	2643 (66.5)	2791 (66.3)
	Missing	4 (1.7)	260 (6.5)	264 (6.3)
	Total	236 (100.0)	3975 (100.0)	4211 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.11. G8P[8]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	585 (0)	3975 (0)	4560 (0)
	Mean (Std)	23.91 (14.082)	17.88 (12.099)	18.65 (12.533)
	Median	20.50	14.40	15.10
	Q1, Q3	14.40, 29.30	9.50, 21.80	10.00, 23.00
	Min, Max	3.8, 77.9	3.7, 77.4	3.7, 77.9
	<=11 months	98 (16.8)	1481 (37.3)	1579 (34.6)
	12-23 months	269 (46.0)	1657 (41.7)	1926 (42.2)
	24-35 months	119 (20.3)	486 (12.2)	605 (13.3)
	>=36 months	99 (16.9)	351 (8.8)	450 (9.9)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	347 (59.3)	2314 (58.2)	2661 (58.4)
	Non-RV peak season	238 (40.7)	1661 (41.8)	1899 (41.6)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)
Residence location (n, %)	Urban	354 (60.5)	2607 (65.6)	2961 (64.9)
	Rural	231 (39.5)	1367 (34.4)	1598 (35.0)
	Missing	0	1 (0.0)	1 (0.0)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)
Regions of study hospitals (n, %) ^[2]	East	269 (46.0)	1980 (49.8)	2249 (49.3)
	Central	175 (29.9)	985 (24.8)	1160 (25.4)
	West	141 (24.1)	1010 (25.4)	1151 (25.2)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)
Clinical settings (n, %)	Inpatient	541 (92.5)	3418 (86.0)	3959 (86.8)
	Outpatient	44 (7.5)	557 (14.0)	601 (13.2)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.11. G8P[8]-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	18 (3.1)	226 (5.7)	244 (5.4)
	2021/10-2022/4	337 (57.6)	1241 (31.2)	1578 (34.6)
	2022/10-2023/4	117 (20.0)	1281 (32.2)	1398 (30.7)
	2024/10-2025/4	113 (19.3)	1227 (30.9)	1340 (29.4)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)
Gender (n, %)	Male	368 (62.9)	2382 (59.9)	2750 (60.3)
	Female	217 (37.1)	1593 (40.1)	1810 (39.7)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)
College and above for either parent's education level (n, %)	No	211 (36.1)	1072 (27.0)	1283 (28.1)
	Yes	348 (59.5)	2643 (66.5)	2991 (65.6)
	Missing	26 (4.4)	260 (6.5)	286 (6.3)
	Total	585 (100.0)	3975 (100.0)	4560 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.12. G9P[8]-Descriptive analysis (Analysis Population)

		<i>Case Group</i> (RV +) <i>N (%)</i>	<i>Control Group</i> (RV -) <i>N (%)</i>	<i>Total</i> <i>N (%)</i>
Age of onset (in months)	n (nmiss)	653 (0)	3975 (0)	4628 (0)
	Mean (Std)	19.74 (10.771)	17.88 (12.099)	18.14 (11.937)
	Median	17.50	14.40	14.90
	Q1, Q3	13.00, 23.40	9.50, 21.80	10.00, 22.10
	Min, Max	4.1, 75.1	3.7, 77.4	3.7, 77.4
	<=11 months	130 (19.9)	1481 (37.3)	1611 (34.8)
	12-23 months	376 (57.6)	1657 (41.7)	2033 (43.9)
	24-35 months	97 (14.9)	486 (12.2)	583 (12.6)
	>=36 months	50 (7.7)	351 (8.8)	401 (8.7)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	390 (59.7)	2314 (58.2)	2704 (58.4)
	Non-RV peak season	263 (40.3)	1661 (41.8)	1924 (41.6)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)
Residence location (n, %)	Urban	403 (61.7)	2607 (65.6)	3010 (65.0)
	Rural	249 (38.1)	1367 (34.4)	1616 (34.9)
	Missing	1 (0.2)	1 (0.0)	2 (0.0)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)
Regions of study hospitals (n, %) ^[2]	East	196 (30.0)	1980 (49.8)	2176 (47.0)
	Central	134 (20.5)	985 (24.8)	1119 (24.2)
	West	323 (49.5)	1010 (25.4)	1333 (28.8)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)
Clinical settings (n, %)	Inpatient	555 (85.0)	3418 (86.0)	3973 (85.8)
	Outpatient	98 (15.0)	557 (14.0)	655 (14.2)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.3.12. G9P[8]-Descriptive analysis (Analysis Population) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Symptom onset seasons (n, %) ^[3]	2020/10-2021/3	350 (53.6)	226 (5.7)	576 (12.4)
	2021/10-2022/4	122 (18.7)	1241 (31.2)	1363 (29.5)
	2022/10-2023/4	60 (9.2)	1281 (32.2)	1341 (29.0)
	2024/10-2025/4	121 (18.5)	1227 (30.9)	1348 (29.1)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)
Gender (n, %)	Male	402 (61.6)	2382 (59.9)	2784 (60.2)
	Female	251 (38.4)	1593 (40.1)	1844 (39.8)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)
College and above for either parent's education level (n, %)	No	93 (14.2)	1072 (27.0)	1165 (25.2)
	Yes	209 (32.0)	2643 (66.5)	2852 (61.6)
	Missing	351 (53.8)	260 (6.5)	611 (13.2)
	Total	653 (100.0)	3975 (100.0)	4628 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Age of onset (in months) (Continuous)	0.018	0.282	1.018 (0.985, 1.052)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.214	0.661	0.808 (0.311, 2.097)
	Residence location (Urban vs Rural)	-1.252	0.014	0.286 (0.106, 0.775)
	Regions of study hospitals (Central vs East)	0.110	0.843	1.117 (0.373, 3.341)
	Regions of study hospitals (West vs East)	-0.425	0.524	0.653 (0.177, 2.419)
	Clinical setting (Inpatient vs Outpatient)	0.201	0.790	1.222 (0.279, 5.358)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	*		
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)			
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)			
	Gender (Male vs Female)	1.138	0.074	3.119 (0.895, 10.870)
G2	Received ROTATEQ vaccination (Yes vs No)	-2.234	0.030	0.107 (0.014, 0.808)
	Age of onset (in months) (Continuous)	-0.003	0.799	0.997 (0.974, 1.021)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.486	0.083	0.615 (0.355, 1.065)
	Residence location (Urban vs Rural)	-0.491	0.079	0.612 (0.353, 1.059)
	Regions of study hospitals (Central vs East)	1.274	0.002	3.574 (1.574, 8.116)
	Regions of study hospitals (West vs East)	1.772	<.001	5.881 (2.755, 12.553)
	Clinical setting (Inpatient vs Outpatient)	-0.499	0.146	0.607 (0.310, 1.189)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	2.657	<.001	14.250 (6.235, 32.567)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.011	0.982	0.989 (0.370, 2.642)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	0.585	0.183	1.796 (0.759, 4.250)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)
(Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G3	Gender (Male vs Female)	0.320	0.282	1.377 (0.769, 2.466)
	Received ROTATEQ vaccination (Yes vs No)	-2.680	<.001	0.069 (0.017, 0.282)
	Age of onset (in months) (Continuous)	0.056	<.001	1.057 (1.050, 1.065)
	Birth seasons (RV peak season vs Non-RV peak season)	0.053	0.693	1.055 (0.810, 1.374)
	Residence location (Urban vs Rural)	-0.361	0.007	0.697 (0.536, 0.908)
	Regions of study hospitals (Central vs East)	-0.368	0.026	0.692 (0.501, 0.957)
	Regions of study hospitals (West vs East)	-0.681	<.001	0.506 (0.353, 0.726)
	Clinical setting (Inpatient vs Outpatient)	0.976	<.001	2.653 (1.535, 4.583)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	-3.710	<.001	0.024 (0.003, 0.175)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-3.622	<.001	0.027 (0.012, 0.060)
G8	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-2.881	<.001	0.056 (0.032, 0.099)
	Gender (Male vs Female)	0.122	0.374	1.129 (0.864, 1.477)
	Received ROTATEQ vaccination (Yes vs No)	-2.506	<.001	0.082 (0.044, 0.150)
	Age of onset (in months) (Continuous)	0.031	<.001	1.032 (1.026, 1.038)
	Birth seasons (RV peak season vs Non-RV peak season)	0.047	0.601	1.048 (0.879, 1.250)
	Residence location (Urban vs Rural)	-0.225	0.013	0.799 (0.669, 0.954)
	Regions of study hospitals (Central vs East)	0.276	0.008	1.318 (1.074, 1.617)
	Regions of study hospitals (West vs East)	0.023	0.832	1.024 (0.824, 1.272)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)
(Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G9	Clinical setting (Inpatient vs Outpatient)	0.700	<.001	2.015 (1.463, 2.775)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	-0.154	0.559	0.857 (0.511, 1.438)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	1.078	<.001	2.940 (2.344, 3.687)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.017	0.901	0.983 (0.751, 1.287)
	Gender (Male vs Female)	0.127	0.165	1.135 (0.949, 1.358)
	Received ROTATEQ vaccination (Yes vs No)	-1.600	<.001	0.202 (0.154, 0.265)
	Age of onset (in months) (Continuous)	0.013	<.001	1.013 (1.007, 1.020)
	Birth seasons (RV peak season vs Non-RV peak season)	0.048	0.575	1.049 (0.888, 1.239)
	Residence location (Urban vs Rural)	-0.156	0.072	0.856 (0.722, 1.014)
	Regions of study hospitals (Central vs East)	0.271	0.021	1.311 (1.042, 1.650)
	Regions of study hospitals (West vs East)	1.124	<.001	3.078 (2.545, 3.722)
	Clinical setting (Inpatient vs Outpatient)	-0.055	0.641	0.946 (0.750, 1.194)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	2.754	<.001	15.709 (12.234, 20.171)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.011	0.933	0.989 (0.760, 1.286)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.599	<.001	0.550 (0.405, 0.745)
P[4]	Gender (Male vs Female)	0.046	0.593	1.047 (0.885, 1.238)
	Received ROTATEQ vaccination (Yes vs No)	-2.325	<.001	0.098 (0.069, 0.138)
	Age of onset (in months) (Continuous)	0.012	0.196	1.012 (0.994, 1.031)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.491	0.054	0.612 (0.372, 1.009)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)
(Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)
P[8]	Residence location (Urban vs Rural)	-0.227	0.382	0.797 (0.479, 1.326)
	Regions of study hospitals (Central vs East)	0.462	0.184	1.587 (0.803, 3.136)
	Regions of study hospitals (West vs East)	1.096	<.001	2.993 (1.670, 5.363)
	Clinical setting (Inpatient vs Outpatient)	-0.261	0.436	0.770 (0.399, 1.485)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	3.036	<.001	20.812 (8.381, 51.683)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.394	0.456	1.483 (0.526, 4.179)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	1.384	0.002	3.991 (1.632, 9.762)
	Gender (Male vs Female)	0.151	0.567	1.163 (0.694, 1.950)
	Received ROTATEQ vaccination (Yes vs No)	-2.153	<.001	0.116 (0.042, 0.320)
	Age of onset (in months) (Continuous)	0.030	<.001	1.031 (1.026, 1.035)
	Birth seasons (RV peak season vs Non-RV peak season)	0.042	0.493	1.043 (0.925, 1.176)
	Residence location (Urban vs Rural)	-0.215	<.001	0.807 (0.714, 0.912)
	Regions of study hospitals (Central vs East)	0.161	0.034	1.175 (1.012, 1.364)
	Regions of study hospitals (West vs East)	0.463	<.001	1.589 (1.383, 1.826)
	Clinical setting (Inpatient vs Outpatient)	0.316	<.001	1.371 (1.138, 1.652)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.478	<.001	4.385 (3.604, 5.336)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.004	0.964	1.004 (0.864, 1.166)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.918	<.001	0.399 (0.332, 0.480)
	Gender (Male vs Female)	0.093	0.134	1.098 (0.972, 1.239)
	Received ROTATEQ vaccination (Yes vs No)	-2.019	<.001	0.133 (0.108, 0.163)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)
(Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1P[8]	Age of onset (in months) (Continuous)	0.018	0.282	1.018 (0.985, 1.052)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.214	0.661	0.808 (0.311, 2.097)
	Residence location (Urban vs Rural)	-1.252	0.014	0.286 (0.106, 0.775)
	Regions of study hospitals (Central vs East)	0.110	0.843	1.117 (0.373, 3.341)
	Regions of study hospitals (West vs East)	-0.425	0.524	0.653 (0.177, 2.419)
	Clinical setting (Inpatient vs Outpatient)	0.201	0.790	1.222 (0.279, 5.358)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	*		
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)			
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)			
	Gender (Male vs Female)	1.138	0.074	3.119 (0.895, 10.870)
G2P[4]	Received ROTATEQ vaccination (Yes vs No)	-2.234	0.030	0.107 (0.014, 0.808)
	Age of onset (in months) (Continuous)	-0.002	0.860	0.998 (0.974, 1.022)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.454	0.115	0.635 (0.361, 1.117)
	Residence location (Urban vs Rural)	-0.358	0.218	0.699 (0.395, 1.235)
	Regions of study hospitals (Central vs East)	1.327	0.003	3.769 (1.593, 8.920)
	Regions of study hospitals (West vs East)	1.852	<.001	6.371 (2.874, 14.123)
	Clinical setting (Inpatient vs Outpatient)	-0.453	0.205	0.636 (0.315, 1.280)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	2.896	<.001	18.097 (7.189, 45.561)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.276	0.610	1.318 (0.456, 3.811)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)
(Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G3P[8]	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	0.873	0.072	2.395 (0.926, 6.192)
	Gender (Male vs Female)	0.416	0.182	1.516 (0.823, 2.792)
	Received ROTATEQ vaccination (Yes vs No)	-2.619	<.001	0.073 (0.018, 0.301)
	Age of onset (in months) (Continuous)	0.055	<.001	1.057 (1.049, 1.065)
	Birth seasons (RV peak season vs Non-RV peak season)	0.099	0.471	1.104 (0.844, 1.444)
	Residence location (Urban vs Rural)	-0.336	0.014	0.715 (0.547, 0.934)
	Regions of study hospitals (Central vs East)	-0.360	0.031	0.697 (0.503, 0.968)
	Regions of study hospitals (West vs East)	-0.680	<.001	0.507 (0.352, 0.730)
	Clinical setting (Inpatient vs Outpatient)	0.949	<.001	2.583 (1.494, 4.465)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	-3.702	<.001	0.025 (0.003, 0.177)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-4.306	<.001	0.013 (0.004, 0.042)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-2.952	<.001	0.052 (0.029, 0.094)
	Gender (Male vs Female)	0.099	0.472	1.105 (0.843, 1.448)
	Received ROTATEQ vaccination (Yes vs No)	-2.480	<.001	0.084 (0.046, 0.154)
G8P[8]	Age of onset (in months) (Continuous)	0.031	<.001	1.032 (1.026, 1.038)
	Birth seasons (RV peak season vs Non-RV peak season)	0.045	0.614	1.047 (0.877, 1.249)
	Residence location (Urban vs Rural)	-0.219	0.016	0.804 (0.672, 0.960)
	Regions of study hospitals (Central vs East)	0.268	0.010	1.308 (1.065, 1.606)
	Regions of study hospitals (West vs East)	0.027	0.806	1.028 (0.827, 1.277)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.4.1. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Analysis Population)
(Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G9P[8]	Clinical setting (Inpatient vs Outpatient)	0.695	<.001	2.004 (1.455, 2.759)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	-0.145	0.582	0.865 (0.516, 1.451)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	1.081	<.001	2.949 (2.349, 3.701)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.008	0.952	0.992 (0.757, 1.299)
	Gender (Male vs Female)	0.126	0.169	1.134 (0.948, 1.357)
	Received ROTATEQ vaccination (Yes vs No)	-1.612	<.001	0.199 (0.152, 0.262)
	Age of onset (in months) (Continuous)	0.012	<.001	1.012 (1.006, 1.019)
	Birth seasons (RV peak season vs Non-RV peak season)	0.062	0.468	1.064 (0.899, 1.260)
	Residence location (Urban vs Rural)	-0.164	0.060	0.849 (0.715, 1.007)
	Regions of study hospitals (Central vs East)	0.318	0.007	1.374 (1.089, 1.734)
	Regions of study hospitals (West vs East)	1.173	<.001	3.231 (2.664, 3.918)
	Clinical setting (Inpatient vs Outpatient)	-0.080	0.499	0.923 (0.731, 1.165)
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	2.754	<.001	15.704 (12.222, 20.179)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.003	0.982	0.997 (0.766, 1.298)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.745	<.001	0.475 (0.345, 0.654)
	Gender (Male vs Female)	0.069	0.428	1.071 (0.904, 1.270)
	Received ROTATEQ vaccination (Yes vs No)	-2.363	<.001	0.094 (0.066, 0.134)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

* Results are not available due to the model convergence issue.

Table 14.4.5.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Analysis Population)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	Residence location (Urban vs Rural) ^[1]	-1.152	0.024	0.316 (0.116, 0.858)	88.02% (9.38%, 98.42%)
	Gender (Male vs Female) ^[1]	1.113	0.081	3.045 (0.872, 10.627)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.122	0.040	0.120 (0.016, 0.906)	
G2	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.399	0.166	0.671 (0.381, 1.180)	90.35% (59.77%, 97.69%)
	Residence location (Urban vs Rural) ^[1]	-0.557	0.059	0.573 (0.321, 1.021)	
	Regions of study hospitals (Central vs East) ^[1]	1.202	0.005	3.327 (1.447, 7.652)	
	Regions of study hospitals (West vs East) ^[1]	1.733	<.001	5.660 (2.611, 12.269)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	2.207	<.001	9.085 (3.918, 21.066)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	-0.173	0.731	0.841 (0.313, 2.258)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.528	0.233	1.695 (0.712, 4.037)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.338	0.001	0.096 (0.023, 0.402)	
G3	Age of onset (in months) (Continuous) ^[1]	0.038	<.001	1.038 (1.030, 1.046)	92.17% (85.44%, 95.79%)
	Residence location (Urban vs Rural) ^[1]	-0.145	0.355	0.865 (0.637, 1.176)	
	Regions of study hospitals (Central vs East) ^[1]	-0.216	0.258	0.806 (0.555, 1.171)	
	Regions of study hospitals (West vs East) ^[1]	-0.320	0.123	0.726 (0.484, 1.091)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.992	0.001	2.696 (1.471, 4.941)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	-3.434	<.001	0.032 (0.004, 0.233)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	-3.382	<.001	0.034 (0.015, 0.077)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-2.724	<.001	0.066 (0.036, 0.119)	
G8	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.548	<.001	0.078 (0.042, 0.146)	
	Age of onset (in months) (Continuous) ^[1]	0.044	<.001	1.045 (1.038, 1.052)	
	Residence location (Urban vs Rural) ^[1]	-0.203	0.040	0.817 (0.673, 0.991)	
	Regions of study hospitals (Central vs East) ^[1]	0.283	0.012	1.327 (1.066, 1.653)	
	Regions of study hospitals (West vs East) ^[1]	0.115	0.334	1.122 (0.888, 1.419)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.715	<.001	2.044 (1.454, 2.872)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	0.269	0.332	1.309 (0.760, 2.253)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	1.411	<.001	4.102 (3.164, 5.318)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.269	0.068	1.309 (0.980, 1.749)	

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.4.4.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.5.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Analysis Population) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.412	<.001	0.244 (0.185, 0.321)	75.64% (67.85%, 81.54%)
G9	Age of onset (in months) (Continuous) ^[1]	0.033	<.001	1.034 (1.026, 1.042)	
	Residence location (Urban vs Rural) ^[1]	-0.160	0.135	0.852 (0.690, 1.051)	
	Regions of study hospitals (Central vs East) ^[1]	0.332	0.015	1.393 (1.065, 1.822)	
	Regions of study hospitals (West vs East) ^[1]	1.167	<.001	3.211 (2.553, 4.040)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	2.711	<.001	15.039 (11.336, 19.953)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.127	0.386	1.135 (0.852, 1.511)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.539	<.001	0.583 (0.424, 0.802)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.842	<.001	0.159 (0.110, 0.228)	84.15% (77.15%, 89.00%)
P[4]	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.406	0.119	0.666 (0.400, 1.110)	
	Regions of study hospitals (Central vs East) ^[1]	0.410	0.245	1.507 (0.755, 3.010)	
	Regions of study hospitals (West vs East) ^[1]	0.972	0.001	2.644 (1.457, 4.795)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	2.654	<.001	14.205 (5.676, 35.551)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.260	0.623	1.297 (0.459, 3.664)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	1.370	0.003	3.936 (1.604, 9.658)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.956	<.001	0.141 (0.051, 0.394)	85.86% (60.55%, 94.93%)
P[8]	Age of onset (in months) (Continuous) ^[1]	0.041	<.001	1.042 (1.036, 1.047)	
	Residence location (Urban vs Rural) ^[1]	-0.182	0.011	0.833 (0.724, 0.959)	
	Regions of study hospitals (Central vs East) ^[1]	0.242	0.005	1.273 (1.075, 1.508)	
	Regions of study hospitals (West vs East) ^[1]	0.574	<.001	1.776 (1.512, 2.085)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.680	<.001	1.973 (1.583, 2.460)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	1.667	<.001	5.294 (4.237, 6.614)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.263	0.002	1.301 (1.099, 1.541)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.716	<.001	0.489 (0.400, 0.597)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.742	<.001	0.175 (0.141, 0.217)	82.49% (78.30%, 85.87%)
G1P[8]	Residence location (Urban vs Rural) ^[1]	-1.152	0.024	0.316 (0.116, 0.858)	
	Gender (Male vs Female) ^[1]	1.113	0.081	3.045 (0.872, 10.627)	

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.4.4.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.5.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Analysis Population) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (% , 95% CI)
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.122	0.040	0.120 (0.016, 0.906)	88.02% (9.38%, 98.42%)
G2P[4]	Regions of study hospitals (Central vs East) ^[1]	1.320	0.003	3.745 (1.566, 8.953)	
	Regions of study hospitals (West vs East) ^[1]	1.757	<.001	5.795 (2.588, 12.976)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	2.496	<.001	12.128 (4.766, 30.863)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.110	0.839	1.117 (0.385, 3.239)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.830	0.088	2.293 (0.883, 5.956)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.348	0.001	0.096 (0.023, 0.399)	90.44% (60.14%, 97.71%)
G3P[8]	Age of onset (in months) (Continuous) ^[1]	0.037	<.001	1.037 (1.029, 1.046)	
	Residence location (Urban vs Rural) ^[1]	-0.120	0.450	0.887 (0.650, 1.210)	
	Regions of study hospitals (Central vs East) ^[1]	-0.214	0.267	0.807 (0.553, 1.178)	
	Regions of study hospitals (West vs East) ^[1]	-0.326	0.120	0.721 (0.478, 1.089)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.963	0.002	2.619 (1.427, 4.806)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	-3.440	<.001	0.032 (0.004, 0.231)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	-4.074	<.001	0.017 (0.005, 0.054)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-2.807	<.001	0.060 (0.033, 0.112)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.527	<.001	0.080 (0.043, 0.149)	92.01% (85.13%, 95.71%)
G8P[8]	Age of onset (in months) (Continuous) ^[1]	0.044	<.001	1.045 (1.038, 1.052)	
	Residence location (Urban vs Rural) ^[1]	-0.197	0.046	0.821 (0.677, 0.996)	
	Regions of study hospitals (Central vs East) ^[1]	0.275	0.014	1.316 (1.056, 1.641)	
	Regions of study hospitals (West vs East) ^[1]	0.118	0.325	1.125 (0.890, 1.422)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.711	<.001	2.037 (1.449, 2.862)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	0.274	0.324	1.315 (0.763, 2.264)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	1.413	<.001	4.106 (3.164, 5.329)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.278	0.061	1.320 (0.988, 1.765)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.424	<.001	0.241 (0.182, 0.318)	75.93% (68.18%, 81.79%)
G9P[8]	Age of onset (in months) (Continuous) ^[1]	0.032	<.001	1.033 (1.025, 1.041)	
	Residence location (Urban vs Rural) ^[1]	-0.166	0.128	0.847 (0.685, 1.049)	

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.4.4.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.4.5.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Analysis Population) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (% , 95% CI)
	Regions of study hospitals (Central vs East) ^[1]	0.399	0.004	1.490 (1.135, 1.956)	
	Regions of study hospitals (West vs East) ^[1]	1.239	<.001	3.451 (2.732, 4.359)	
	Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	2.692	<.001	14.757 (11.114, 19.594)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.118	0.419	1.125 (0.845, 1.499)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.705	<.001	0.494 (0.354, 0.689)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.872	<.001	0.154 (0.106, 0.224)	84.62% (77.59%, 89.44%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.4.4.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Table 14.5.1. Crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	117 (7.1)	1465 (36.0)	1582 (27.7)	86.38% (83.38%, 88.83%)
Unvaccinated	1529 (92.9)	2608 (64.0)	4137 (72.3)	
Total	1646 (100.0)	4073 (100.0)	5719 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.1.1. G8-Crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

	<i>Case Group (RV +) N (%)</i>	<i>Control Group (RV -) N (%)</i>	<i>Total N (%)</i>	<i>VE (%, 95% CI)</i>
Vaccinated	62 (10.3)	1465 (36.0)	1527 (32.6)	79.64% (73.31%, 84.46%)
Unvaccinated	542 (89.7)	2608 (64.0)	3150 (67.4)	
Total	604 (100.0)	4073 (100.0)	4677 (100.0)	

The denominator is the number of patients in each group within analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Age of onset group	<=11 months	Vaccinated	21 (7.3)	520 (34.3)	541 (30.0)	84.93% (76.21%, 90.46%)
		Unvaccinated	267 (92.7)	996 (65.7)	1263 (70.0)	
		Total	288 (100.0)	1516 (100.0)	1804 (100.0)	
	12-23 months	Vaccinated	58 (7.1)	655 (38.6)	713 (28.3)	87.87% (83.88%, 90.87%)
		Unvaccinated	762 (92.9)	1044 (61.4)	1806 (71.7)	
		Total	820 (100.0)	1699 (100.0)	2519 (100.0)	
	24-35 months	Vaccinated	23 (8.2)	182 (36.5)	205 (26.4)	84.40% (75.19%, 90.19%)
		Unvaccinated	256 (91.8)	316 (63.5)	572 (73.6)	
		Total	279 (100.0)	498 (100.0)	777 (100.0)	
	>=36 months	Vaccinated	15 (5.8)	108 (30.0)	123 (19.9)	85.66% (74.69%, 91.87%)
		Unvaccinated	244 (94.2)	252 (70.0)	496 (80.1)	
		Total	259 (100.0)	360 (100.0)	619 (100.0)	
Birth seasons	RV peak season ^[1]	Vaccinated	68 (7.1)	870 (36.8)	938 (28.3)	86.91% (83.01%, 89.91%)
		Unvaccinated	890 (92.9)	1491 (63.2)	2381 (71.7)	
		Total	958 (100.0)	2361 (100.0)	3319 (100.0)	
	Non-RV peak season	Vaccinated	49 (7.1)	595 (34.8)	644 (26.8)	85.60% (80.43%, 89.41%)
		Unvaccinated	639 (92.9)	1117 (65.2)	1756 (73.2)	
		Total	688 (100.0)	1712 (100.0)	2400 (100.0)	
Residence location	Urban	Vaccinated	78 (7.8)	1030 (38.5)	1108 (30.2)	86.47% (82.73%, 89.40%)
		Unvaccinated	920 (92.2)	1644 (61.5)	2564 (69.8)	
		Total	998 (100.0)	2674 (100.0)	3672 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1) (Continued)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Regions of study hospitals ^[2]	Rural	Vaccinated	38 (5.9)	434 (31.1)	472 (23.1)	86.09% (80.32%, 90.16%)
		Unvaccinated	606 (94.1)	963 (68.9)	1569 (76.9)	
		Total	644 (100.0)	1397 (100.0)	2041 (100.0)	
	East	Vaccinated	54 (8.0)	752 (37.4)	806 (30.0)	85.46% (80.53%, 89.15%)
		Unvaccinated	622 (92.0)	1259 (62.6)	1881 (70.0)	
		Total	676 (100.0)	2011 (100.0)	2687 (100.0)	
	Central	Vaccinated	17 (4.2)	338 (33.1)	355 (24.9)	91.11% (85.30%, 94.62%)
		Unvaccinated	387 (95.8)	684 (66.9)	1071 (75.1)	
		Total	404 (100.0)	1022 (100.0)	1426 (100.0)	
Clinical setting	West	Vaccinated	46 (8.1)	375 (36.1)	421 (26.2)	84.31% (78.25%, 88.69%)
		Unvaccinated	520 (91.9)	665 (63.9)	1185 (73.8)	
		Total	566 (100.0)	1040 (100.0)	1606 (100.0)	
	Inpatient	Vaccinated	97 (6.6)	1244 (35.6)	1341 (27.0)	87.14% (84.01%, 89.65%)
		Unvaccinated	1365 (93.4)	2252 (64.4)	3617 (73.0)	
		Total	1462 (100.0)	3496 (100.0)	4958 (100.0)	
	Outpatient	Vaccinated	20 (10.9)	221 (38.3)	241 (31.7)	80.36% (67.82%, 88.01%)
		Unvaccinated	164 (89.1)	356 (61.7)	520 (68.3)	
		Total	184 (100.0)	577 (100.0)	761 (100.0)	
Symptom onset seasons ^[3]	2020/10-2021/3	Vaccinated	10 (2.4)	30 (13.2)	40 (6.1)	84.01% (66.65%, 92.34%)
		Unvaccinated	413 (97.6)	198 (86.8)	611 (93.9)	
		Total	423 (100.0)	228 (100.0)	651 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

**Table 14.5.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1)
 (Continued)**

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Gender	2021/10-2022/4	Vaccinated	51 (9.9)	395 (30.2)	446 (24.5)	74.53% (65.20%, 81.36%)
		Unvaccinated	463 (90.1)	913 (69.8)	1376 (75.5)	
		Total	514 (100.0)	1308 (100.0)	1822 (100.0)	
	2022/10-2023/4	Vaccinated	29 (12.8)	552 (42.4)	581 (38.0)	80.10% (70.17%, 86.73%)
		Unvaccinated	198 (87.2)	750 (57.6)	948 (62.0)	
		Total	227 (100.0)	1302 (100.0)	1529 (100.0)	
	2024/10-2025/4	Vaccinated	27 (5.6)	488 (39.5)	515 (30.0)	90.91% (86.38%, 93.94%)
		Unvaccinated	455 (94.4)	747 (60.5)	1202 (70.0)	
		Total	482 (100.0)	1235 (100.0)	1717 (100.0)	
	Male	Vaccinated	69 (6.8)	860 (35.2)	929 (26.8)	86.60% (82.65%, 89.65%)
		Unvaccinated	949 (93.2)	1585 (64.8)	2534 (73.2)	
		Total	1018 (100.0)	2445 (100.0)	3463 (100.0)	
	Female	Vaccinated	48 (7.6)	605 (37.2)	653 (28.9)	86.01% (80.90%, 89.75%)
		Unvaccinated	580 (92.4)	1023 (62.8)	1603 (71.1)	
		Total	628 (100.0)	1628 (100.0)	2256 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.2.1. G8-Subgroup analysis of crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Age of onset group	<=11 months	Vaccinated	13 (13.1)	520 (34.3)	533 (33.0)	71.05% (47.62%, 84.00%)
		Unvaccinated	86 (86.9)	996 (65.7)	1082 (67.0)	
		Total	99 (100.0)	1516 (100.0)	1615 (100.0)	
	12-23 months	Vaccinated	29 (10.2)	655 (38.6)	684 (34.5)	81.80% (72.95%, 87.76%)
		Unvaccinated	254 (89.8)	1044 (61.4)	1298 (65.5)	
		Total	283 (100.0)	1699 (100.0)	1982 (100.0)	
	24-35 months	Vaccinated	14 (11.5)	182 (36.5)	196 (31.6)	77.49% (59.57%, 87.47%)
		Unvaccinated	108 (88.5)	316 (63.5)	424 (68.4)	
		Total	122 (100.0)	498 (100.0)	620 (100.0)	
	>=36 months	Vaccinated	6 (6.0)	108 (30.0)	114 (24.8)	85.11% (64.96%, 93.67%)
		Unvaccinated	94 (94.0)	252 (70.0)	346 (75.2)	
		Total	100 (100.0)	360 (100.0)	460 (100.0)	
Birth seasons	RV peak season ^[1]	Vaccinated	36 (10.1)	870 (36.8)	906 (33.3)	80.84% (72.69%, 86.56%)
		Unvaccinated	322 (89.9)	1491 (63.2)	1813 (66.7)	
		Total	358 (100.0)	2361 (100.0)	2719 (100.0)	
	Non-RV peak season	Vaccinated	26 (10.6)	595 (34.8)	621 (31.7)	77.81% (66.29%, 85.40%)
		Unvaccinated	220 (89.4)	1117 (65.2)	1337 (68.3)	
		Total	246 (100.0)	1712 (100.0)	1958 (100.0)	
Residence location	Urban	Vaccinated	42 (11.4)	1030 (38.5)	1072 (35.3)	79.37% (71.29%, 85.18%)
		Unvaccinated	325 (88.6)	1644 (61.5)	1969 (64.7)	
		Total	367 (100.0)	2674 (100.0)	3041 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.2.1. G8-Subgroup analysis of crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1) (Continued)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Regions of study hospitals ^[2]	Rural	Vaccinated	20 (8.4)	434 (31.1)	454 (27.8)	79.55% (67.22%, 87.24%)
		Unvaccinated	217 (91.6)	963 (68.9)	1180 (72.2)	
		Total	237 (100.0)	1397 (100.0)	1634 (100.0)	
	East	Vaccinated	33 (12.2)	752 (37.4)	785 (34.4)	76.79% (66.22%, 84.05%)
		Unvaccinated	238 (87.8)	1259 (62.6)	1497 (65.6)	
		Total	271 (100.0)	2011 (100.0)	2282 (100.0)	
	Central	Vaccinated	9 (4.9)	338 (33.1)	347 (28.8)	89.59% (79.40%, 94.74%)
		Unvaccinated	175 (95.1)	684 (66.9)	859 (71.2)	
		Total	184 (100.0)	1022 (100.0)	1206 (100.0)	
	West	Vaccinated	20 (13.4)	375 (36.1)	395 (33.2)	72.51% (55.22%, 83.12%)
		Unvaccinated	129 (86.6)	665 (63.9)	794 (66.8)	
		Total	149 (100.0)	1040 (100.0)	1189 (100.0)	
Clinical setting	Inpatient	Vaccinated	56 (10.0)	1244 (35.6)	1300 (32.1)	79.81% (73.15%, 84.81%)
		Unvaccinated	502 (90.0)	2252 (64.4)	2754 (67.9)	
		Total	558 (100.0)	3496 (100.0)	4054 (100.0)	
	Outpatient	Vaccinated	6 (13.0)	221 (38.3)	227 (36.4)	75.84% (42.08%, 89.92%)
		Unvaccinated	40 (87.0)	356 (61.7)	396 (63.6)	
		Total	46 (100.0)	577 (100.0)	623 (100.0)	
Symptom onset seasons ^[3]	2020/10-2021/3	Vaccinated	1 (5.6)	30 (13.2)	31 (12.6)	61.16% (-202.50%, 95.01%)
		Unvaccinated	17 (94.4)	198 (86.8)	215 (87.4)	
		Total	18 (100.0)	228 (100.0)	246 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.2.1. G8-Subgroup analysis of crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1) (Continued)

			Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
	2021/10-2022/4	Vaccinated	31 (8.7)	395 (30.2)	426 (25.6)	77.88% (67.44%, 84.98%)
		Unvaccinated	324 (91.3)	913 (69.8)	1237 (74.4)	
		Total	355 (100.0)	1308 (100.0)	1663 (100.0)	
	2022/10-2023/4	Vaccinated	20 (17.1)	552 (42.4)	572 (40.3)	71.99% (54.10%, 82.90%)
		Unvaccinated	97 (82.9)	750 (57.6)	847 (59.7)	
		Total	117 (100.0)	1302 (100.0)	1419 (100.0)	
	2024/10-2025/4	Vaccinated	10 (8.8)	488 (39.5)	498 (36.9)	85.28% (71.55%, 92.38%)
		Unvaccinated	104 (91.2)	747 (60.5)	851 (63.1)	
		Total	114 (100.0)	1235 (100.0)	1349 (100.0)	
Gender	Male	Vaccinated	37 (9.7)	860 (35.2)	897 (31.8)	80.12% (71.81%, 85.98%)
		Unvaccinated	343 (90.3)	1585 (64.8)	1928 (68.2)	
		Total	380 (100.0)	2445 (100.0)	2825 (100.0)	
	Female	Vaccinated	25 (11.2)	605 (37.2)	630 (34.0)	78.76% (67.41%, 86.15%)
		Unvaccinated	199 (88.8)	1023 (62.8)	1222 (66.0)	
		Total	224 (100.0)	1628 (100.0)	1852 (100.0)	

The denominator is the number of patients in each subgroup within each group of analysis population.

Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ following the recommended schedule; Unvaccinated denotes children who haven't received any rotavirus vaccines.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.3. Demographic and clinical characteristics of RVGE case and control groups (Sensitivity analysis 1)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Age of onset (in months)	n (nmiss)	1646 (0)	4073 (0)	5719 (0)
	Mean (Std)	23.13 (14.244)	17.86 (12.060)	19.38 (12.948)
	Median	19.20	14.40	15.70
	Q1, Q3	13.80, 28.10	9.50, 21.80	10.50, 23.60
	Min, Max	3.8, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	288 (17.5)	1516 (37.2)	1804 (31.5)
	12-23 months	820 (49.8)	1699 (41.7)	2519 (44.0)
	24-35 months	279 (17.0)	498 (12.2)	777 (13.6)
	>=36 months	259 (15.7)	360 (8.8)	619 (10.8)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	958 (58.2)	2361 (58.0)	3319 (58.0)
	Non-RV peak season	688 (41.8)	1712 (42.0)	2400 (42.0)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
Residence location (n, %)	Urban	998 (60.6)	2674 (65.7)	3672 (64.2)
	Rural	644 (39.1)	1397 (34.3)	2041 (35.7)
	Missing	4 (0.2)	2 (0.0)	6 (0.1)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
Regions of study hospitals (n, %) ^[2]	East	676 (41.1)	2011 (49.4)	2687 (47.0)
	Central	404 (24.5)	1022 (25.1)	1426 (24.9)
	West	566 (34.4)	1040 (25.5)	1606 (28.1)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
Clinical settings (n, %)	Inpatient	1462 (88.8)	3496 (85.8)	4958 (86.7)
	Outpatient	184 (11.2)	577 (14.2)	761 (13.3)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.3. Demographic and clinical characteristics of RVGE case and control groups (Sensitivity analysis 1) (Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	423 (25.7)	228 (5.6)	651 (11.4)
	2021/10-2022/4	514 (31.2)	1308 (32.1)	1822 (31.9)
	2022/10-2023/4	227 (13.8)	1302 (32.0)	1529 (26.7)
	2024/10-2025/4	482 (29.3)	1235 (30.3)	1717 (30.0)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
Gender (n, %)	Male	1018 (61.8)	2445 (60.0)	3463 (60.6)
	Female	628 (38.2)	1628 (40.0)	2256 (39.4)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)
College and above for either parent's education level (n, %)	No	432 (26.2)	1105 (27.1)	1537 (26.9)
	Yes	776 (47.1)	2703 (66.4)	3479 (60.8)
	Missing	438 (26.6)	265 (6.5)	703 (12.3)
	Total	1646 (100.0)	4073 (100.0)	5719 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

[1] October to April of the following year.

[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.3.1. G8-Demographic and clinical characteristics of RVGE case and control groups (Sensitivity analysis 1)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
Age of onset (in months)	n (nmiss)	604 (0)	4073 (0)	4677 (0)
	Mean (Std)	23.76 (13.943)	17.86 (12.060)	18.63 (12.476)
	Median	20.35	14.40	15.10
	Q1, Q3	14.35, 29.20	9.50, 21.80	10.00, 23.00
	Min, Max	3.8, 77.9	3.7, 77.4	3.7, 77.9
	<=11 months	99 (16.4)	1516 (37.2)	1615 (34.5)
	12-23 months	283 (46.9)	1699 (41.7)	1982 (42.4)
	24-35 months	122 (20.2)	498 (12.2)	620 (13.3)
	>=36 months	100 (16.6)	360 (8.8)	460 (9.8)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
Birth seasons (n, %) ^[1]	RV peak season	358 (59.3)	2361 (58.0)	2719 (58.1)
	Non-RV peak season	246 (40.7)	1712 (42.0)	1958 (41.9)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
Residence location (n, %)	Urban	367 (60.8)	2674 (65.7)	3041 (65.0)
	Rural	237 (39.2)	1397 (34.3)	1634 (34.9)
	Missing	0	2 (0.0)	2 (0.0)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
Regions of study hospitals (n, %) ^[2]	East	271 (44.9)	2011 (49.4)	2282 (48.8)
	Central	184 (30.5)	1022 (25.1)	1206 (25.8)
	West	149 (24.7)	1040 (25.5)	1189 (25.4)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
Clinical settings (n, %)	Inpatient	558 (92.4)	3496 (85.8)	4054 (86.7)
	Outpatient	46 (7.6)	577 (14.2)	623 (13.3)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

^[1] October to April of the following year.

^[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

^[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.3.1. G8-Demographic and clinical characteristics of RVGE case and control groups (Sensitivity analysis 1)
(Continued)

		Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	18 (3.0)	228 (5.6)	246 (5.3)
	2021/10-2022/4	355 (58.8)	1308 (32.1)	1663 (35.6)
	2022/10-2023/4	117 (19.4)	1302 (32.0)	1419 (30.3)
	2024/10-2025/4	114 (18.9)	1235 (30.3)	1349 (28.8)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
Gender (n, %)	Male	380 (62.9)	2445 (60.0)	2825 (60.4)
	Female	224 (37.1)	1628 (40.0)	1852 (39.6)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)
College and above for either parent's education level (n, %)	No	218 (36.1)	1105 (27.1)	1323 (28.3)
	Yes	358 (59.3)	2703 (66.4)	3061 (65.4)
	Missing	28 (4.6)	265 (6.5)	293 (6.3)
	Total	604 (100.0)	4073 (100.0)	4677 (100.0)

The denominator is the number of patients in each group within analysis population.

Nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

[1] October to April of the following year.

[2] East (Beijing, Hebei, Jiangsu, Zhejiang, Fujian, Shandong and Guangdong); Central (Anhui, Henan, Hubei and Hunan); West (Chongqing, Sichuan, Yunnan and Shaanxi).

[3] Patients with AGE onset who visited the hospital between September 23 and September 30 and met the inclusion criteria were included in the symptom onset season.

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.4. Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Age of onset (in months) (Continuous)	0.029	<.001	1.030 (1.025, 1.034)
Birth seasons (RV peak season vs Non-RV peak season)	0.010	0.871	1.010 (0.899, 1.134)
Residence location (Urban vs Rural)	-0.211	<.001	0.810 (0.719, 0.911)
Regions of study hospitals (Central vs East)	0.162	0.028	1.176 (1.018, 1.359)
Regions of study hospitals (West vs East)	0.482	<.001	1.619 (1.415, 1.852)
Clinical setting (Inpatient vs Outpatient)	0.271	0.003	1.311 (1.099, 1.565)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.559	<.001	4.754 (3.922, 5.762)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.007	0.927	1.007 (0.870, 1.166)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.806	<.001	0.447 (0.375, 0.533)
Gender (Male vs Female)	0.076	0.203	1.079 (0.960, 1.214)
Received ROTATEQ vaccination (Yes vs No)	-1.993	<.001	0.136 (0.112, 0.166)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.
 Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.4.1. G8-Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Age of onset (in months) (Continuous)	0.031	<.001	1.031 (1.025, 1.037)
Birth seasons (RV peak season vs Non-RV peak season)	0.054	0.544	1.055 (0.887, 1.256)
Residence location (Urban vs Rural)	-0.212	0.018	0.809 (0.679, 0.964)
Regions of study hospitals (Central vs East)	0.290	0.005	1.336 (1.092, 1.635)
Regions of study hospitals (West vs East)	0.061	0.574	1.063 (0.859, 1.316)
Clinical setting (Inpatient vs Outpatient)	0.694	<.001	2.002 (1.464, 2.739)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	-0.156	0.553	0.855 (0.510, 1.434)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	1.078	<.001	2.940 (2.348, 3.682)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.027	0.845	0.974 (0.744, 1.275)
Gender (Male vs Female)	0.122	0.176	1.130 (0.947, 1.348)
Received ROTATEQ vaccination (Yes vs No)	-1.591	<.001	0.204 (0.155, 0.267)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.
 Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.5. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Age of onset (in months) (Continuous) ^[1]	0.040	<.001	1.041 (1.036, 1.047)	
Residence location (Urban vs Rural) ^[1]	-0.189	0.007	0.828 (0.722, 0.949)	
Regions of study hospitals (Central vs East) ^[1]	0.239	0.004	1.270 (1.078, 1.496)	
Regions of study hospitals (West vs East) ^[1]	0.582	<.001	1.789 (1.531, 2.090)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.668	<.001	1.951 (1.580, 2.408)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	1.771	<.001	5.874 (4.720, 7.311)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.249	0.003	1.283 (1.087, 1.513)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.608	<.001	0.544 (0.450, 0.659)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.714	<.001	0.180 (0.146, 0.222)	81.99% (77.84%, 85.36%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.4, potential confounders which are significantly different ($P < 0.1$) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Unconditional multivariate logistic regression was performed using a sample size of 5713 (including 1642 cases and 4071 controls).

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.5.1. G8-Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Age of onset (in months) (Continuous) ^[1]	0.044	<.001	1.044 (1.037, 1.052)	
Residence location (Urban vs Rural) ^[1]	-0.205	0.035	0.814 (0.673, 0.986)	
Regions of study hospitals (Central vs East) ^[1]	0.282	0.011	1.325 (1.067, 1.646)	
Regions of study hospitals (West vs East) ^[1]	0.141	0.230	1.151 (0.914, 1.449)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.715	<.001	2.044 (1.466, 2.849)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	0.265	0.338	1.304 (0.758, 2.243)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	1.393	<.001	4.028 (3.114, 5.211)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.243	0.099	1.275 (0.955, 1.702)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.392	<.001	0.249 (0.189, 0.328)	75.14% (67.21%, 81.15%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.4.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Unconditional multivariate logistic regression was performed using a sample size of 4675 (including 604 cases and 4071 controls).

Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.5.6. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 2)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Age of onset (in months) (Continuous) ^[1]	0.041	<.001	1.041 (1.036, 1.047)	
Residence location (Urban vs Rural) ^[2]	-0.181	0.010	0.834 (0.727, 0.958)	
Regions of study hospitals (Central vs East) ^[2]	0.234	0.006	1.264 (1.070, 1.491)	
Regions of study hospitals (West vs East) ^[2]	0.578	<.001	1.782 (1.523, 2.085)	
Clinical setting (Inpatient vs Outpatient) ^[2]	0.668	<.001	1.949 (1.573, 2.415)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	1.774	<.001	5.894 (4.731, 7.342)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.273	0.001	1.314 (1.112, 1.554)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.590	<.001	0.555 (0.458, 0.672)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[1]	-1.732	<.001	0.177 (0.144, 0.218)	82.31% (78.23%, 85.63%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] "Age of onset (in months)", "symptom onset seasons" and "received ROTATEQ vaccination" are the fixed variables in the logistic regression.

^[2] Refer to the results of Table 14.3.4, potential confounders which are significantly ($P < 0.1$) different between case and controls group will be included in model.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Unconditional multivariate logistic regression was performed using a sample size of 5590 (including 1616 cases and 3974 controls).

Sensitivity analysis 2: Age of onset (in months) and symptom onset seasons are considered important confounders and will be directly included in the unconditional multivariate logistic regression model, regardless of their P-values in the univariate logistic regression, even if $P \geq 0.1$.

Table 14.5.6.1. G8-Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 2)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Age of onset (in months) (Continuous) ^[1]	0.044	<.001	1.045 (1.038, 1.052)	
Residence location (Urban vs Rural) ^[2]	-0.203	0.040	0.817 (0.673, 0.991)	
Regions of study hospitals (Central vs East) ^[2]	0.283	0.012	1.327 (1.066, 1.653)	
Regions of study hospitals (West vs East) ^[2]	0.115	0.334	1.122 (0.888, 1.419)	
Clinical setting (Inpatient vs Outpatient) ^[2]	0.715	<.001	2.044 (1.454, 2.872)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) ^[1]	0.269	0.332	1.309 (0.760, 2.253)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	1.411	<.001	4.102 (3.164, 5.318)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.269	0.068	1.309 (0.980, 1.749)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[1]	-1.412	<.001	0.244 (0.185, 0.321)	75.64% (67.85%, 81.54%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] "Age of onset (in months)", "symptom onset seasons" and "received ROTATEQ vaccination" are the fixed variables in the logistic regression.

^[2] Refer to the results of Table 14.4.4.1, potential confounders which are significantly ($P < 0.1$) different between case and controls group will be included in model.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Unconditional multivariate logistic regression was performed using a sample size of 4562 (including 588 cases and 3974 controls).

Sensitivity analysis 2: Age of onset (in months) and symptom onset seasons are considered important confounders and will be directly included in the unconditional multivariate logistic regression model, regardless of their P-values in the univariate logistic regression, even if $P \geq 0.1$.

Table 14.5.7.1. Conditional Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 3-1:1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Birth seasons (RV peak season vs Non-RV peak season)	-0.051	0.581	0.950 (0.793, 1.138)
Residence location (Urban vs Rural)	-0.124	0.147	0.884 (0.747, 1.045)
Regions of study hospitals (Central vs East)	0.268	0.008	1.308 (1.071, 1.597)
Regions of study hospitals (West vs East)	0.363	<.001	1.437 (1.188, 1.739)
Clinical setting (Inpatient vs Outpatient)	0.608	<.001	1.837 (1.399, 2.413)
Received ROTATEQ vaccination (Yes vs No)	-1.735	<.001	0.176 (0.136, 0.229)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.5.7.2. Conditional Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 3-1:2)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Birth seasons (RV peak season vs Non-RV peak season)	-0.045	0.559	0.956 (0.820, 1.113)
Residence location (Urban vs Rural)	-0.080	0.284	0.923 (0.798, 1.069)
Regions of study hospitals (Central vs East)	0.250	0.005	1.284 (1.076, 1.531)
Regions of study hospitals (West vs East)	0.373	<.001	1.452 (1.229, 1.716)
Clinical setting (Inpatient vs Outpatient)	0.632	<.001	1.881 (1.473, 2.403)
Received ROTATEQ vaccination (Yes vs No)	-1.719	<.001	0.179 (0.142, 0.226)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.5.7.3. Conditional Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 3-1:3)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Birth seasons (RV peak season vs Non-RV peak season)	-0.007	0.926	0.993 (0.859, 1.149)
Residence location (Urban vs Rural)	-0.071	0.325	0.932 (0.809, 1.073)
Regions of study hospitals (Central vs East)	0.289	<.001	1.336 (1.125, 1.585)
Regions of study hospitals (West vs East)	0.399	<.001	1.490 (1.268, 1.751)
Clinical setting (Inpatient vs Outpatient)	0.634	<.001	1.884 (1.481, 2.398)
Received ROTATEQ vaccination (Yes vs No)	-1.743	<.001	0.175 (0.140, 0.219)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.5.8.1. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 3-1:1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Regions of study hospitals (Central vs East) ^[1]	0.215	0.059	1.239 (0.992, 1.549)	
Regions of study hospitals (West vs East) ^[1]	0.397	<.001	1.488 (1.200, 1.844)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.643	<.001	1.902 (1.403, 2.579)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.739	<.001	0.176 (0.135, 0.229)	82.43% (77.11%, 86.52%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.7.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Conditional multivariate logistic regression was performed using a sample size of 2360 (including 1180 cases and 1180 controls).

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.5.8.2. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 3-1:2)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Regions of study hospitals (Central vs East) ^[1]	0.181	0.060	1.198 (0.993, 1.446)	
Regions of study hospitals (West vs East) ^[1]	0.384	<.001	1.468 (1.227, 1.757)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.546	<.001	1.726 (1.329, 2.240)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.696	<.001	0.183 (0.146, 0.231)	81.66% (76.88%, 85.45%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.7.2, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Conditional multivariate logistic regression was performed using a sample size of 3410 (including 1180 cases and 2230 controls).

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.5.8.3. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 3-1:3)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Regions of study hospitals (Central vs East) ^[1]	0.223	0.015	1.250 (1.044, 1.498)	
Regions of study hospitals (West vs East) ^[1]	0.421	<.001	1.523 (1.283, 1.809)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.542	<.001	1.720 (1.334, 2.218)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.725	<.001	0.178 (0.142, 0.223)	82.19% (77.72%, 85.76%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.7.3, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Conditional multivariate logistic regression was performed using a sample size of 4037 (including 1180 cases and 2857 controls).

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.5.9.1. Conditional Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 4-1:1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Birth seasons (RV peak season vs Non-RV peak season)	0.017	0.821	1.017 (0.877, 1.180)
Residence location (Urban vs Rural)	-0.343	<.001	0.709 (0.613, 0.821)
Regions of study hospitals (Central vs East)	0.251	0.005	1.286 (1.078, 1.534)
Regions of study hospitals (West vs East)	0.382	<.001	1.465 (1.247, 1.722)
Clinical setting (Inpatient vs Outpatient)	0.514	<.001	1.671 (1.361, 2.052)
Received ROTATEQ vaccination (Yes vs No)	-1.909	<.001	0.148 (0.116, 0.189)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.5.9.2. Conditional Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 4-1:2)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Birth seasons (RV peak season vs Non-RV peak season)	-0.024	0.725	0.976 (0.854, 1.116)
Residence location (Urban vs Rural)	-0.273	<.001	0.761 (0.668, 0.866)
Regions of study hospitals (Central vs East)	0.303	<.001	1.354 (1.154, 1.589)
Regions of study hospitals (West vs East)	0.436	<.001	1.547 (1.335, 1.793)
Clinical setting (Inpatient vs Outpatient)	0.495	<.001	1.641 (1.356, 1.986)
Received ROTATEQ vaccination (Yes vs No)	-1.923	<.001	0.146 (0.117, 0.182)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.5.9.3. Conditional Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 4-1:3)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Birth seasons (RV peak season vs Non-RV peak season)	0.013	0.850	1.013 (0.889, 1.154)
Residence location (Urban vs Rural)	-0.263	<.001	0.769 (0.677, 0.873)
Regions of study hospitals (Central vs East)	0.251	0.001	1.285 (1.102, 1.500)
Regions of study hospitals (West vs East)	0.446	<.001	1.561 (1.352, 1.804)
Clinical setting (Inpatient vs Outpatient)	0.478	<.001	1.613 (1.335, 1.950)
Received ROTATEQ vaccination (Yes vs No)	-1.933	<.001	0.145 (0.117, 0.180)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.5.10.1. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 4-1:1)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Residence location (Urban vs Rural) ^[1]	-0.271	0.002	0.763 (0.644, 0.903)	
Regions of study hospitals (Central vs East) ^[1]	0.142	0.155	1.153 (0.948, 1.403)	
Regions of study hospitals (West vs East) ^[1]	0.524	<.001	1.688 (1.400, 2.037)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.502	<.001	1.651 (1.299, 2.100)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.898	<.001	0.150 (0.117, 0.192)	85.01% (80.78%, 88.32%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.9.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Conditional multivariate logistic regression was performed using a sample size of 3230 (including 1615 cases and 1615 controls).

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.5.10.2. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 4-1:2)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Residence location (Urban vs Rural) ^[1]	-0.171	0.022	0.843 (0.729, 0.975)	
Regions of study hospitals (Central vs East) ^[1]	0.215	0.015	1.240 (1.044, 1.474)	
Regions of study hospitals (West vs East) ^[1]	0.538	<.001	1.713 (1.451, 2.021)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.527	<.001	1.693 (1.366, 2.099)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.913	<.001	0.148 (0.118, 0.184)	85.24% (81.57%, 88.18%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.9.2, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Conditional multivariate logistic regression was performed using a sample size of 4326 (including 1615 cases and 2711 controls).

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.5.10.3. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 4-1:3)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Residence location (Urban vs Rural) ^[1]	-0.181	0.012	0.835 (0.725, 0.961)	
Regions of study hospitals (Central vs East) ^[1]	0.169	0.045	1.184 (1.004, 1.396)	
Regions of study hospitals (West vs East) ^[1]	0.538	<.001	1.713 (1.460, 2.011)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.500	<.001	1.649 (1.334, 2.038)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.915	<.001	0.147 (0.118, 0.183)	85.27% (81.68%, 88.16%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.9.3, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Conditional multivariate logistic regression was performed using a sample size of 4899 (including 1615 cases and 3284 controls).

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.5.11. Univariate Logistic Regression (Primary Endpoint-Sensitivity analysis 5)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
Age of onset (in months) (Continuous)	0.037	<.001	1.037 (1.033, 1.042)
Birth seasons (RV peak season vs Non-RV peak season)	-0.012	0.856	0.988 (0.865, 1.128)
Residence location (Urban vs Rural)	-0.146	0.034	0.864 (0.754, 0.989)
Regions of study hospitals (Central vs East)	0.136	0.101	1.146 (0.974, 1.348)
Regions of study hospitals (West vs East)	0.334	<.001	1.396 (1.195, 1.630)
Clinical setting (Inpatient vs Outpatient)	0.501	<.001	1.651 (1.312, 2.078)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.012	0.870	1.013 (0.872, 1.175)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.795	<.001	0.452 (0.378, 0.539)
Gender (Male vs Female)	0.118	0.088	1.125 (0.983, 1.287)
College and above for either parent's education level (Yes vs No)	-0.321	<.001	0.725 (0.632, 0.833)
Received ROTATEQ vaccination (Yes vs No)	-1.840	<.001	0.159 (0.129, 0.196)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

Table 14.5.12. Adjusted vaccine effectiveness against RVGE cases (Sensitivity analysis 5)

<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>	<i>VE (% , 95% CI)</i>
Age of onset (in months) (Continuous) ^[1]	0.040	<.001	1.040 (1.035, 1.046)	
Residence location (Urban vs Rural) ^[1]	-0.134	0.087	0.875 (0.750, 1.020)	
Regions of study hospitals (Central vs East) ^[1]	0.235	0.010	1.265 (1.058, 1.512)	
Regions of study hospitals (West vs East) ^[1]	0.525	<.001	1.691 (1.422, 2.010)	
Clinical setting (Inpatient vs Outpatient) ^[1]	0.562	<.001	1.755 (1.363, 2.259)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.247	0.004	1.280 (1.081, 1.515)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.587	<.001	0.556 (0.459, 0.674)	
Gender (Male vs Female) ^[1]	0.098	0.189	1.103 (0.953, 1.277)	
College and above for either parent's education level (Yes vs No) ^[1]	-0.085	0.285	0.919 (0.786, 1.073)	
Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.721	<.001	0.179 (0.144, 0.223)	82.11% (77.75%, 85.61%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.5.11, potential confounders which are significantly different ($P < 0.1$) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Unconditional multivariate logistic regression was performed using a sample size of 4897 (including 1183 cases and 3714 controls).

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

Table 14.6.1.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:1)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Birth seasons (RV peak season vs Non-RV peak season)	0.000	1.000	1.000 (0.250, 3.998)
	Residence location (Urban vs Rural)	-1.504	0.054	0.222 (0.048, 1.028)
	Regions of study hospitals (Central vs East)	0.468	0.633	1.597 (0.233, 10.938)
	Regions of study hospitals (West vs East)	0.313	0.766	1.367 (0.174, 10.764)
	Clinical setting (Inpatient vs Outpatient)	-0.693	0.571	0.500 (0.045, 5.514)
	Received ROTATEQ vaccination (Yes vs No)	-1.099	0.341	0.333 (0.035, 3.205)
G2	Birth seasons (RV peak season vs Non-RV peak season)	-0.811	0.177	0.444 (0.137, 1.443)
	Residence location (Urban vs Rural)	-1.253	0.118	0.286 (0.059, 1.375)
	Regions of study hospitals (Central vs East)	1.119	0.255	3.061 (0.446, 20.989)
	Regions of study hospitals (West vs East)	1.460	0.072	4.307 (0.878, 21.123)
	Clinical setting (Inpatient vs Outpatient)	1.792	0.097	6.000 (0.722, 49.837)
	Received ROTATEQ vaccination (Yes vs No)	-2.565	0.013	0.077 (0.010, 0.588)
G3	Birth seasons (RV peak season vs Non-RV peak season)	*		
	Residence location (Urban vs Rural)	-0.277	0.152	0.758 (0.519, 1.107)
	Regions of study hospitals (Central vs East)	-0.048	0.837	0.953 (0.603, 1.506)
	Regions of study hospitals (West vs East)	-0.555	0.032	0.574 (0.345, 0.954)
	Clinical setting (Inpatient vs Outpatient)	1.003	0.004	2.727 (1.367, 5.442)
	Received ROTATEQ vaccination (Yes vs No)	-2.485	<.001	0.083 (0.036, 0.192)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8	Birth seasons (RV peak season vs Non-RV peak season)	-0.056	0.659	0.946 (0.738, 1.211)
	Residence location (Urban vs Rural)	-0.275	0.025	0.760 (0.597, 0.966)
	Regions of study hospitals (Central vs East)	0.559	<.001	1.749 (1.295, 2.361)
	Regions of study hospitals (West vs East)	0.088	0.552	1.092 (0.817, 1.458)
	Clinical setting (Inpatient vs Outpatient)	0.721	<.001	2.057 (1.374, 3.081)
	Received ROTATEQ vaccination (Yes vs No)	-1.565	<.001	0.209 (0.147, 0.298)
G9	Birth seasons (RV peak season vs Non-RV peak season)	-0.110	0.508	0.896 (0.648, 1.240)
	Residence location (Urban vs Rural)	0.275	0.108	1.317 (0.941, 1.842)
	Regions of study hospitals (Central vs East)	0.246	0.266	1.279 (0.829, 1.973)
	Regions of study hospitals (West vs East)	1.207	<.001	3.344 (2.263, 4.942)
	Clinical setting (Inpatient vs Outpatient)	0.295	0.187	1.343 (0.867, 2.080)
	Received ROTATEQ vaccination (Yes vs No)	-1.721	<.001	0.179 (0.114, 0.282)
P[4]	Birth seasons (RV peak season vs Non-RV peak season)	-0.182	0.670	0.833 (0.360, 1.929)
	Residence location (Urban vs Rural)	-0.318	0.493	0.727 (0.293, 1.808)
	Regions of study hospitals (Central vs East)	0.164	0.769	1.178 (0.396, 3.502)
	Regions of study hospitals (West vs East)	0.925	0.098	2.521 (0.842, 7.547)
	Clinical setting (Inpatient vs Outpatient)	2.079	0.050	8.000 (1.001, 63.963)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
P[8]	Received ROTATEQ vaccination (Yes vs No)	-2.773	0.007	0.063 (0.008, 0.471)
	Birth seasons (RV peak season vs Non-RV peak season)	0.004	0.965	1.004 (0.844, 1.194)
	Residence location (Urban vs Rural)	0.004	0.965	1.004 (0.844, 1.194)
	Regions of study hospitals (Central vs East)	0.232	0.028	1.261 (1.025, 1.552)
	Regions of study hospitals (West vs East)	0.371	<.001	1.449 (1.186, 1.770)
G1P[8]	Clinical setting (Inpatient vs Outpatient)	0.530	<.001	1.699 (1.295, 2.228)
	Received ROTATEQ vaccination (Yes vs No)	-1.740	<.001	0.175 (0.134, 0.229)
	Birth seasons (RV peak season vs Non-RV peak season)	0.000	1.000	1.000 (0.250, 3.998)
	Residence location (Urban vs Rural)	-1.504	0.054	0.222 (0.048, 1.028)
	Regions of study hospitals (Central vs East)	0.468	0.633	1.597 (0.233, 10.938)
G2P[4]	Regions of study hospitals (West vs East)	0.313	0.766	1.367 (0.174, 10.764)
	Clinical setting (Inpatient vs Outpatient)	-0.693	0.571	0.500 (0.045, 5.514)
	Received ROTATEQ vaccination (Yes vs No)	-1.099	0.341	0.333 (0.035, 3.205)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.588	0.292	0.556 (0.186, 1.658)
	Residence location (Urban vs Rural)	-0.288	0.594	0.750 (0.260, 2.162)
	Regions of study hospitals (Central vs East)	1.055	0.134	2.871 (0.722, 11.420)
	Regions of study hospitals (West vs East)	1.650	0.017	5.206 (1.345, 20.155)
	Clinical setting (Inpatient vs Outpatient)	1.609	0.142	5.000 (0.584, 42.797)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G3P[8]	Received ROTATEQ vaccination (Yes vs No)	-19.203	0.996	<0.001 (<0.001, >999.999)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.018	0.924	0.982 (0.677, 1.425)
	Residence location (Urban vs Rural)	-0.195	0.302	0.823 (0.568, 1.191)
	Regions of study hospitals (Central vs East)	0.054	0.820	1.056 (0.663, 1.682)
	Regions of study hospitals (West vs East)	-0.448	0.066	0.639 (0.396, 1.030)
G8P[8]	Clinical setting (Inpatient vs Outpatient)	0.860	0.017	2.364 (1.168, 4.783)
	Received ROTATEQ vaccination (Yes vs No)	-2.590	<.001	0.075 (0.033, 0.172)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.055	0.685	0.946 (0.726, 1.234)
	Residence location (Urban vs Rural)	-0.274	0.032	0.761 (0.592, 0.977)
	Regions of study hospitals (Central vs East)	0.461	0.002	1.585 (1.181, 2.129)
G9P[8]	Regions of study hospitals (West vs East)	0.128	0.392	1.137 (0.847, 1.526)
	Clinical setting (Inpatient vs Outpatient)	1.001	<.001	2.722 (1.858, 3.989)
	Received ROTATEQ vaccination (Yes vs No)	-1.580	<.001	0.206 (0.143, 0.296)
	Birth seasons (RV peak season vs Non-RV peak season)	0.029	0.866	1.029 (0.739, 1.433)
	Residence location (Urban vs Rural)	0.201	0.274	1.222 (0.853, 1.751)
	Regions of study hospitals (Central vs East)	0.406	0.074	1.500 (0.962, 2.340)
	Regions of study hospitals (West vs East)	1.093	<.001	2.984 (2.018, 4.412)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
	Clinical setting (Inpatient vs Outpatient)	0.318	0.170	1.375 (0.872, 2.168)
	Received ROTATEQ vaccination (Yes vs No)	-1.917	<.001	0.147 (0.086, 0.253)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:2)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Birth seasons (RV peak season vs Non-RV peak season)	0.137	0.831	1.147 (0.326, 4.035)
	Residence location (Urban vs Rural)	-1.783	0.007	0.168 (0.046, 0.615)
	Regions of study hospitals (Central vs East)	0.370	0.608	1.448 (0.352, 5.953)
	Regions of study hospitals (West vs East)	-0.457	0.572	0.633 (0.130, 3.090)
	Clinical setting (Inpatient vs Outpatient)	0.223	0.790	1.250 (0.243, 6.443)
	Received ROTATEQ vaccination (Yes vs No)	-1.724	0.108	0.178 (0.022, 1.458)
G2	Birth seasons (RV peak season vs Non-RV peak season)	-0.949	0.082	0.387 (0.133, 1.129)
	Residence location (Urban vs Rural)	-0.083	0.868	0.920 (0.346, 2.449)
	Regions of study hospitals (Central vs East)	1.463	0.067	4.320 (0.901, 20.703)
	Regions of study hospitals (West vs East)	1.538	0.020	4.657 (1.268, 17.099)
	Clinical setting (Inpatient vs Outpatient)	1.813	0.088	6.131 (0.761, 49.381)
	Received ROTATEQ vaccination (Yes vs No)	-2.805	0.007	0.061 (0.008, 0.467)
G3	Birth seasons (RV peak season vs Non-RV peak season)	-0.112	0.494	0.894 (0.648, 1.233)
	Residence location (Urban vs Rural)	-0.248	0.132	0.780 (0.565, 1.077)
	Regions of study hospitals (Central vs East)	-0.074	0.716	0.929 (0.625, 1.381)
	Regions of study hospitals (West vs East)	-0.597	0.008	0.551 (0.355, 0.854)
	Clinical setting (Inpatient vs Outpatient)	1.014	0.003	2.756 (1.410, 5.388)
	Received ROTATEQ vaccination (Yes vs No)	-2.385	<.001	0.092 (0.048, 0.177)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:2) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8	Birth seasons (RV peak season vs Non-RV peak season)	-0.033	0.767	0.968 (0.779, 1.203)
	Residence location (Urban vs Rural)	*		
	Regions of study hospitals (Central vs East)	0.489	<.001	1.631 (1.273, 2.089)
	Regions of study hospitals (West vs East)	0.090	0.487	1.094 (0.850, 1.408)
	Clinical setting (Inpatient vs Outpatient)	0.745	<.001	2.106 (1.454, 3.049)
	Received ROTATEQ vaccination (Yes vs No)	-1.544	<.001	0.214 (0.157, 0.290)
G9	Birth seasons (RV peak season vs Non-RV peak season)	-0.083	0.563	0.920 (0.694, 1.220)
	Residence location (Urban vs Rural)	0.304	0.047	1.356 (1.005, 1.829)
	Regions of study hospitals (Central vs East)	0.268	0.168	1.307 (0.893, 1.913)
	Regions of study hospitals (West vs East)	1.252	<.001	3.499 (2.521, 4.856)
	Clinical setting (Inpatient vs Outpatient)	0.213	0.294	1.237 (0.831, 1.841)
	Received ROTATEQ vaccination (Yes vs No)	-1.628	<.001	0.196 (0.130, 0.296)
P[4]	Birth seasons (RV peak season vs Non-RV peak season)	-0.504	0.200	0.604 (0.279, 1.306)
	Residence location (Urban vs Rural)	-0.058	0.890	0.944 (0.419, 2.129)
	Regions of study hospitals (Central vs East)	0.437	0.424	1.548 (0.531, 4.514)
	Regions of study hospitals (West vs East)	1.081	0.024	2.947 (1.155, 7.523)
	Clinical setting (Inpatient vs Outpatient)	2.040	0.052	7.690 (0.984, 60.085)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:2) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
P[8]	Received ROTATEQ vaccination (Yes vs No)	-2.501	<.001	0.082 (0.019, 0.357)
	Birth seasons (RV peak season vs Non-RV peak season)	0.002	0.979	1.002 (0.860, 1.168)
	Residence location (Urban vs Rural)	-0.037	0.635	0.964 (0.829, 1.121)
	Regions of study hospitals (Central vs East)	0.306	<.001	1.358 (1.134, 1.626)
	Regions of study hospitals (West vs East)	0.412	<.001	1.510 (1.268, 1.798)
G1P[8]	Clinical setting (Inpatient vs Outpatient)	0.588	<.001	1.801 (1.411, 2.298)
	Received ROTATEQ vaccination (Yes vs No)	-1.734	<.001	0.177 (0.140, 0.223)
	Birth seasons (RV peak season vs Non-RV peak season)	0.137	0.831	1.147 (0.326, 4.035)
	Residence location (Urban vs Rural)	-1.783	0.007	0.168 (0.046, 0.615)
	Regions of study hospitals (Central vs East)	0.370	0.608	1.448 (0.352, 5.953)
G2P[4]	Regions of study hospitals (West vs East)	-0.457	0.572	0.633 (0.130, 3.090)
	Clinical setting (Inpatient vs Outpatient)	0.223	0.790	1.250 (0.243, 6.443)
	Received ROTATEQ vaccination (Yes vs No)	-1.724	0.108	0.178 (0.022, 1.458)
	Birth seasons (RV peak season vs Non-RV peak season)	*		
	Residence location (Urban vs Rural)	0.072	0.877	1.074 (0.432, 2.673)
	Regions of study hospitals (Central vs East)	1.240	0.057	3.457 (0.963, 12.406)
	Regions of study hospitals (West vs East)	2.070	0.002	7.928 (2.101, 29.923)
	Clinical setting (Inpatient vs Outpatient)	1.386	0.211	4.000 (0.456, 35.078)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:2) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)
G3P[8]	Received ROTATEQ vaccination (Yes vs No)	-18.358	0.993	<0.001 (<0.001, >999.999)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.160	0.333	0.852 (0.616, 1.178)
	Residence location (Urban vs Rural)	*		
	Regions of study hospitals (Central vs East)	0.132	0.536	1.142 (0.750, 1.737)
	Regions of study hospitals (West vs East)	-0.429	0.048	0.651 (0.426, 0.996)
G8P[8]	Clinical setting (Inpatient vs Outpatient)	0.912	0.005	2.489 (1.309, 4.733)
	Received ROTATEQ vaccination (Yes vs No)	-2.852	<.001	0.058 (0.027, 0.125)
	Birth seasons (RV peak season vs Non-RV peak season)	0.007	0.954	1.007 (0.803, 1.262)
	Residence location (Urban vs Rural)	-0.264	0.014	0.768 (0.621, 0.948)
	Regions of study hospitals (Central vs East)	0.421	0.001	1.524 (1.186, 1.959)
G9P[8]	Regions of study hospitals (West vs East)	0.053	0.679	1.055 (0.820, 1.357)
	Clinical setting (Inpatient vs Outpatient)	0.819	<.001	2.267 (1.593, 3.228)
	Received ROTATEQ vaccination (Yes vs No)	-1.537	<.001	0.215 (0.158, 0.293)
	Birth seasons (RV peak season vs Non-RV peak season)	0.035	0.810	1.035 (0.780, 1.374)
	Residence location (Urban vs Rural)	0.161	0.303	1.175 (0.865, 1.596)
	Regions of study hospitals (Central vs East)	0.362	0.073	1.437 (0.967, 2.134)
	Regions of study hospitals (West vs East)	1.146	<.001	3.147 (2.266, 4.371)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:2) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
	Clinical setting (Inpatient vs Outpatient)	0.200	0.325	1.221 (0.820, 1.817)
	Received ROTATEQ vaccination (Yes vs No)	-1.820	<.001	0.162 (0.103, 0.256)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

Table 14.6.1.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:3)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Birth seasons (RV peak season vs Non-RV peak season)	0.103	0.873	1.108 (0.315, 3.904)
	Residence location (Urban vs Rural)	-1.472	0.017	0.229 (0.069, 0.765)
	Regions of study hospitals (Central vs East)	0.467	0.477	1.595 (0.441, 5.776)
	Regions of study hospitals (West vs East)	-0.033	0.965	0.967 (0.219, 4.268)
	Clinical setting (Inpatient vs Outpatient)	0.000	1.000	1.000 (0.202, 4.955)
	Received ROTATEQ vaccination (Yes vs No)	-1.536	0.151	0.215 (0.026, 1.751)
G2	Birth seasons (RV peak season vs Non-RV peak season)	-0.855	0.065	0.425 (0.172, 1.053)
	Residence location (Urban vs Rural)	-0.148	0.739	0.862 (0.361, 2.061)
	Regions of study hospitals (Central vs East)	1.044	0.085	2.841 (0.866, 9.325)
	Regions of study hospitals (West vs East)	1.356	0.008	3.882 (1.426, 10.566)
	Clinical setting (Inpatient vs Outpatient)	1.800	0.086	6.050 (0.775, 47.229)
	Received ROTATEQ vaccination (Yes vs No)	-3.172	0.002	0.042 (0.005, 0.320)
G3	Birth seasons (RV peak season vs Non-RV peak season)	-0.120	0.442	0.887 (0.654, 1.204)
	Residence location (Urban vs Rural)	-0.161	0.303	0.851 (0.627, 1.156)
	Regions of study hospitals (Central vs East)	-0.029	0.881	0.971 (0.664, 1.421)
	Regions of study hospitals (West vs East)	-0.428	0.045	0.652 (0.428, 0.991)
	Clinical setting (Inpatient vs Outpatient)	1.065	<.001	2.900 (1.538, 5.466)
	Received ROTATEQ vaccination (Yes vs No)	-2.496	<.001	0.082 (0.043, 0.158)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.1.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:3) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8	Birth seasons (RV peak season vs Non-RV peak season)	-0.038	0.720	0.963 (0.784, 1.183)
	Residence location (Urban vs Rural)	-0.275	0.006	0.760 (0.625, 0.924)
	Regions of study hospitals (Central vs East)	0.430	<.001	1.538 (1.221, 1.936)
	Regions of study hospitals (West vs East)	0.066	0.587	1.069 (0.841, 1.358)
	Clinical setting (Inpatient vs Outpatient)	0.701	<.001	2.015 (1.417, 2.865)
	Received ROTATEQ vaccination (Yes vs No)	-1.518	<.001	0.219 (0.163, 0.294)
G9	Birth seasons (RV peak season vs Non-RV peak season)	-0.069	0.609	0.933 (0.715, 1.217)
	Residence location (Urban vs Rural)	0.336	0.018	1.399 (1.059, 1.847)
	Regions of study hospitals (Central vs East)	0.318	0.092	1.375 (0.949, 1.992)
	Regions of study hospitals (West vs East)	1.259	<.001	3.523 (2.594, 4.786)
	Clinical setting (Inpatient vs Outpatient)	0.174	0.371	1.190 (0.813, 1.742)
	Received ROTATEQ vaccination (Yes vs No)	-1.617	<.001	0.198 (0.133, 0.297)
P[4]	Birth seasons (RV peak season vs Non-RV peak season)	-0.577	0.134	0.562 (0.264, 1.194)
	Residence location (Urban vs Rural)	-0.295	0.469	0.745 (0.336, 1.653)
	Regions of study hospitals (Central vs East)	0.531	0.311	1.700 (0.609, 4.750)
	Regions of study hospitals (West vs East)	0.969	0.030	2.635 (1.098, 6.327)
	Clinical setting (Inpatient vs Outpatient)	1.856	0.076	6.396 (0.825, 49.595)
	Received ROTATEQ vaccination (Yes vs No)	-2.405	0.001	0.090 (0.021, 0.385)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.1.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:3) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.021	0.780	1.021 (0.882, 1.182)
	Residence location (Urban vs Rural)	-0.060	0.415	0.941 (0.814, 1.088)
	Regions of study hospitals (Central vs East)	0.320	<.001	1.377 (1.157, 1.639)
	Regions of study hospitals (West vs East)	0.427	<.001	1.532 (1.295, 1.812)
	Clinical setting (Inpatient vs Outpatient)	0.559	<.001	1.749 (1.377, 2.222)
	Received ROTATEQ vaccination (Yes vs No)	-1.724	<.001	0.178 (0.142, 0.223)
G1P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.103	0.873	1.108 (0.315, 3.904)
	Residence location (Urban vs Rural)	-1.472	0.017	0.229 (0.069, 0.765)
	Regions of study hospitals (Central vs East)	0.467	0.477	1.595 (0.441, 5.776)
	Regions of study hospitals (West vs East)	-0.033	0.965	0.967 (0.219, 4.268)
	Clinical setting (Inpatient vs Outpatient)	0.000	1.000	1.000 (0.202, 4.955)
	Received ROTATEQ vaccination (Yes vs No)	-1.536	0.151	0.215 (0.026, 1.751)
G2P[4]	Birth seasons (RV peak season vs Non-RV peak season)	-0.048	0.913	0.953 (0.403, 2.251)
	Residence location (Urban vs Rural)	0.208	0.651	1.231 (0.500, 3.033)
	Regions of study hospitals (Central vs East)	0.878	0.123	2.407 (0.789, 7.348)
	Regions of study hospitals (West vs East)	1.795	0.001	6.020 (2.043, 17.734)
	Clinical setting (Inpatient vs Outpatient)	1.230	0.292	3.421 (0.347, 33.682)
	Received ROTATEQ vaccination (Yes vs No)	-2.996	0.004	0.050 (0.007, 0.383)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.1.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 3-1:3) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G3P[8]	Birth seasons (RV peak season vs Non-RV peak season)	-0.108	0.498	0.898 (0.657, 1.226)
	Residence location (Urban vs Rural)	-0.176	0.260	0.838 (0.617, 1.139)
	Regions of study hospitals (Central vs East)	-0.027	0.893	0.974 (0.661, 1.435)
	Regions of study hospitals (West vs East)	-0.415	0.051	0.660 (0.435, 1.002)
	Clinical setting (Inpatient vs Outpatient)	0.973	0.003	2.645 (1.407, 4.974)
	Received ROTATEQ vaccination (Yes vs No)	-2.822	<.001	0.059 (0.028, 0.128)
G8P[8]	Birth seasons (RV peak season vs Non-RV peak season)	-0.041	0.705	0.960 (0.777, 1.186)
	Residence location (Urban vs Rural)	-0.251	0.013	0.778 (0.639, 0.948)
	Regions of study hospitals (Central vs East)	0.430	<.001	1.538 (1.218, 1.941)
	Regions of study hospitals (West vs East)	0.124	0.308	1.132 (0.892, 1.438)
	Clinical setting (Inpatient vs Outpatient)	0.748	<.001	2.113 (1.493, 2.990)
	Received ROTATEQ vaccination (Yes vs No)	-1.531	<.001	0.216 (0.161, 0.291)
G9P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.037	0.781	1.038 (0.798, 1.350)
	Residence location (Urban vs Rural)	0.273	0.063	1.314 (0.985, 1.753)
	Regions of study hospitals (Central vs East)	0.342	0.073	1.408 (0.968, 2.047)
	Regions of study hospitals (West vs East)	1.274	<.001	3.575 (2.608, 4.899)
	Clinical setting (Inpatient vs Outpatient)	0.140	0.471	1.150 (0.787, 1.681)
	Received ROTATEQ vaccination (Yes vs No)	-1.781	<.001	0.169 (0.109, 0.261)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.2.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 3-1:1)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	Residence location (Urban vs Rural) ^[1]	-1.498	0.063	0.224 (0.046, 1.082)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.076	0.424	0.341 (0.024, 4.757)	65.90% (-375.67%, 97.55%)
G2	Regions of study hospitals (Central vs East) ^[1]	2.187	0.131	8.909 (0.520, 152.494)	
	Regions of study hospitals (West vs East) ^[1]	2.428	0.095	11.342 (0.656, 196.195)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	2.603	0.145	13.508 (0.406, 448.933)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.722	0.020	0.066 (0.007, 0.647)	93.43% (35.28%, 99.33%)
G3	Regions of study hospitals (Central vs East) ^[1]	-0.131	0.628	0.877 (0.516, 1.491)	
	Regions of study hospitals (West vs East) ^[1]	-0.622	0.048	0.537 (0.290, 0.995)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.891	0.022	2.437 (1.135, 5.233)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.423	<.001	0.089 (0.038, 0.205)	91.13% (79.45%, 96.17%)
G8	Residence location (Urban vs Rural) ^[1]	-0.095	0.497	0.910 (0.692, 1.196)	
	Regions of study hospitals (Central vs East) ^[1]	0.488	0.004	1.629 (1.173, 2.263)	
	Regions of study hospitals (West vs East) ^[1]	0.236	0.156	1.266 (0.914, 1.753)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.582	0.010	1.790 (1.148, 2.791)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.515	<.001	0.220 (0.153, 0.315)	78.02% (68.47%, 84.68%)
G9	Regions of study hospitals (Central vs East) ^[1]	0.295	0.252	1.343 (0.811, 2.223)	
	Regions of study hospitals (West vs East) ^[1]	1.277	<.001	3.585 (2.301, 5.586)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.775	<.001	0.170 (0.105, 0.275)	83.05% (72.52%, 89.55%)
P[4]	Regions of study hospitals (Central vs East) ^[1]	-1.264	0.177	0.282 (0.045, 1.771)	
	Regions of study hospitals (West vs East) ^[1]	-0.327	0.675	0.721 (0.157, 3.319)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	3.013	0.044	20.343 (1.085, 381.253)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.510	0.007	0.030 (0.002, 0.391)	97.01% (60.94%, 99.77%)
P[8]	Regions of study hospitals (Central vs East) ^[1]	0.224	0.056	1.252 (0.995, 1.575)	
	Regions of study hospitals (West vs East) ^[1]	0.453	<.001	1.572 (1.251, 1.976)	

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.1.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.6.2.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 3-1:1) (Continued)

Types	Factors	Regression P Value Coefficient		OR (95% CI)	VE (%; 95% CI)
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.456	0.004	1.577 (1.161, 2.143)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.728	<.001	0.178 (0.135, 0.233)	82.24% (76.73%, 86.45%)
G1P[8]	Residence location (Urban vs Rural) ^[1]	-1.498	0.063	0.224 (0.046, 1.082)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.076	0.424	0.341 (0.024, 4.757)	65.90% (-375.67%, 97.55%)
G2P[4]	Regions of study hospitals (Central vs East) ^[1]	0.131	0.898	1.140 (0.154, 8.456)	
	Regions of study hospitals (West vs East) ^[1]	1.996	0.081	7.363 (0.782, 69.335)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-19.440	0.996	<0.001 (<0.001, >999.999)	100.00% (NA, 100.00%)
G3P[8]	Regions of study hospitals (Central vs East) ^[1]	0.083	0.769	1.086 (0.626, 1.886)	
	Regions of study hospitals (West vs East) ^[1]	-0.550	0.066	0.577 (0.320, 1.038)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.581	0.176	1.788 (0.771, 4.149)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.587	<.001	0.075 (0.033, 0.174)	92.48% (82.59%, 96.75%)
G8P[8]	Residence location (Urban vs Rural) ^[1]	-0.177	0.223	0.837 (0.630, 1.114)	
	Regions of study hospitals (Central vs East) ^[1]	0.229	0.172	1.257 (0.905, 1.745)	
	Regions of study hospitals (West vs East) ^[1]	0.174	0.307	1.190 (0.852, 1.664)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.903	<.001	2.466 (1.626, 3.740)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.525	<.001	0.218 (0.150, 0.316)	78.24% (68.42%, 85.00%)
G9P[8]	Regions of study hospitals (Central vs East) ^[1]	0.265	0.281	1.304 (0.805, 2.112)	
	Regions of study hospitals (West vs East) ^[1]	0.946	<.001	2.576 (1.685, 3.939)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.826	<.001	0.161 (0.093, 0.280)	83.89% (71.97%, 90.74%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.1.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.6.2.2. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 3-1:2)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	Residence location (Urban vs Rural) ^[1]	-1.632	0.016	0.196 (0.052, 0.739)	78.04% (-152.40%, 98.09%)
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.516	0.224	0.220 (0.019, 2.524)	
G2	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.590	0.364	0.554 (0.155, 1.980)	95.97% (58.76%, 99.61%)
	Regions of study hospitals (Central vs East) ^[1]	2.060	0.033	7.848 (1.182, 52.118)	
	Regions of study hospitals (West vs East) ^[1]	1.821	0.026	6.178 (1.240, 30.769)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.012	0.371	2.750 (0.299, 25.267)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.211	0.007	0.040 (0.004, 0.412)	
G3	Regions of study hospitals (Central vs East) ^[1]	-0.041	0.857	0.960 (0.614, 1.500)	89.75% (80.19%, 94.70%)
	Regions of study hospitals (West vs East) ^[1]	-0.520	0.038	0.594 (0.363, 0.972)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.762	0.034	2.142 (1.058, 4.338)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.278	<.001	0.103 (0.053, 0.198)	
G8	Regions of study hospitals (Central vs East) ^[1]	0.468	<.001	1.596 (1.224, 2.082)	78.19% (70.31%, 83.98%)
	Regions of study hospitals (West vs East) ^[1]	0.181	0.190	1.198 (0.914, 1.570)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.597	0.003	1.817 (1.232, 2.679)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.523	<.001	0.218 (0.160, 0.297)	
G9	Residence location (Urban vs Rural) ^[1]	0.233	0.179	1.262 (0.899, 1.773)	81.74% (71.74%, 88.20%)
	Regions of study hospitals (Central vs East) ^[1]	0.252	0.225	1.287 (0.857, 1.932)	
	Regions of study hospitals (West vs East) ^[1]	1.240	<.001	3.455 (2.414, 4.945)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.700	<.001	0.183 (0.118, 0.283)	
P[4]	Regions of study hospitals (Central vs East) ^[1]	0.159	0.805	1.173 (0.330, 4.170)	92.36% (61.04%, 98.50%)
	Regions of study hospitals (West vs East) ^[1]	0.722	0.167	2.059 (0.740, 5.730)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	2.192	0.058	8.957 (0.926, 86.615)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.571	0.002	0.076 (0.015, 0.390)	
P[8]	Regions of study hospitals (Central vs East) ^[1]	0.292	0.003	1.339 (1.103, 1.625)	

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.1.2, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.6.2.2. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 3-1:2) (Continued)

Types	Factors	Regression P Value		OR (95% CI)	VE (%; 95% CI)
		Coefficient			
	Regions of study hospitals (West vs East) ^[1]	0.440	<.001	1.552 (1.283, 1.878)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.492	<.001	1.635 (1.256, 2.129)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.716	<.001	0.180 (0.142, 0.227)	82.01% (77.27%, 85.77%)
G1P[8]	Residence location (Urban vs Rural) ^[1]	-1.632	0.016	0.196 (0.052, 0.739)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.516	0.224	0.220 (0.019, 2.524)	78.04% (-152.40%, 98.09%)
G2P[4]	Regions of study hospitals (Central vs East) ^[1]	0.294	0.710	1.341 (0.286, 6.299)	
	Regions of study hospitals (West vs East) ^[1]	1.813	0.046	6.129 (1.035, 36.293)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-18.117	0.993	<0.001 (<0.001, >999.999)	100.00% (NA, 100.00%)
G3P[8]	Regions of study hospitals (Central vs East) ^[1]	0.146	0.555	1.157 (0.712, 1.881)	
	Regions of study hospitals (West vs East) ^[1]	-0.352	0.169	0.703 (0.425, 1.161)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.519	0.171	1.681 (0.799, 3.539)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.800	<.001	0.061 (0.028, 0.132)	93.92% (86.82%, 97.19%)
G8P[8]	Residence location (Urban vs Rural) ^[1]	-0.201	0.087	0.818 (0.650, 1.030)	
	Regions of study hospitals (Central vs East) ^[1]	0.285	0.038	1.329 (1.015, 1.740)	
	Regions of study hospitals (West vs East) ^[1]	0.140	0.322	1.150 (0.872, 1.518)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.718	<.001	2.051 (1.415, 2.973)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.507	<.001	0.222 (0.162, 0.303)	77.84% (69.65%, 83.82%)
G9P[8]	Regions of study hospitals (Central vs East) ^[1]	0.343	0.102	1.409 (0.934, 2.127)	
	Regions of study hospitals (West vs East) ^[1]	1.092	<.001	2.980 (2.105, 4.218)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.780	<.001	0.169 (0.105, 0.270)	83.14% (73.05%, 89.45%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.1.2, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.6.2.3. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 3-1:3)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	Residence location (Urban vs Rural) ^[1]	-1.366	0.031	0.255 (0.074, 0.882)	73.20% (-149.11%, 97.12%)
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.317	0.247	0.268 (0.029, 2.491)	
G2	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.196	0.732	0.822 (0.267, 2.526)	96.46% (68.21%, 99.61%)
	Regions of study hospitals (Central vs East) ^[1]	1.413	0.077	4.107 (0.856, 19.702)	
	Regions of study hospitals (West vs East) ^[1]	1.584	0.022	4.875 (1.259, 18.875)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.319	0.240	3.740 (0.415, 33.747)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.341	0.003	0.035 (0.004, 0.318)	
G3	Regions of study hospitals (Central vs East) ^[1]	-0.107	0.619	0.899 (0.590, 1.370)	91.08% (82.82%, 95.37%)
	Regions of study hospitals (West vs East) ^[1]	-0.449	0.059	0.638 (0.400, 1.018)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.826	0.015	2.284 (1.175, 4.440)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.417	<.001	0.089 (0.046, 0.172)	
G8	Residence location (Urban vs Rural) ^[1]	-0.176	0.105	0.839 (0.678, 1.037)	77.38% (69.57%, 83.19%)
	Regions of study hospitals (Central vs East) ^[1]	0.414	<.001	1.512 (1.187, 1.926)	
	Regions of study hospitals (West vs East) ^[1]	0.192	0.144	1.212 (0.936, 1.570)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.563	0.003	1.755 (1.219, 2.528)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.486	<.001	0.226 (0.168, 0.304)	
G9	Residence location (Urban vs Rural) ^[1]	0.302	0.053	1.353 (0.996, 1.837)	82.03% (72.57%, 88.22%)
	Regions of study hospitals (Central vs East) ^[1]	0.305	0.121	1.357 (0.922, 1.997)	
	Regions of study hospitals (West vs East) ^[1]	1.245	<.001	3.474 (2.502, 4.824)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.716	<.001	0.180 (0.118, 0.274)	
P[4]	Regions of study hospitals (Central vs East) ^[1]	0.369	0.520	1.447 (0.470, 4.451)	89.89% (56.54%, 97.65%)
	Regions of study hospitals (West vs East) ^[1]	0.700	0.144	2.014 (0.788, 5.147)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.529	0.148	4.612 (0.582, 36.568)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.292	0.002	0.101 (0.023, 0.435)	

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.1.3, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.2.3. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 3-1:3) (Continued)

Types	Factors	Regression P Value		OR (95% CI)	VE (%; 95% CI)
		Coefficient			
P[8]	Regions of study hospitals (Central vs East) ^[1]	0.289	0.002	1.335 (1.110, 1.605)	
	Regions of study hospitals (West vs East) ^[1]	0.450	<.001	1.569 (1.310, 1.879)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.461	<.001	1.585 (1.228, 2.046)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.705	<.001	0.182 (0.145, 0.228)	81.83% (77.22%, 85.51%)
G1P[8]	Residence location (Urban vs Rural) ^[1]	-1.366	0.031	0.255 (0.074, 0.882)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.317	0.247	0.268 (0.029, 2.491)	73.20% (-149.11%, 97.12%)
G2P[4]	Regions of study hospitals (Central vs East) ^[1]	0.187	0.769	1.205 (0.346, 4.195)	
	Regions of study hospitals (West vs East) ^[1]	1.923	0.006	6.844 (1.727, 27.126)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.404	0.003	0.033 (0.003, 0.326)	96.68% (67.42%, 99.66%)
G3P[8]	Regions of study hospitals (Central vs East) ^[1]	-0.091	0.679	0.913 (0.594, 1.403)	
	Regions of study hospitals (West vs East) ^[1]	-0.315	0.181	0.730 (0.460, 1.158)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.641	0.058	1.898 (0.977, 3.685)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.752	<.001	0.064 (0.030, 0.138)	93.62% (86.20%, 97.05%)
G8P[8]	Residence location (Urban vs Rural) ^[1]	-0.171	0.112	0.843 (0.682, 1.041)	
	Regions of study hospitals (Central vs East) ^[1]	0.351	0.005	1.420 (1.112, 1.814)	
	Regions of study hospitals (West vs East) ^[1]	0.222	0.090	1.248 (0.966, 1.613)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.677	<.001	1.967 (1.368, 2.827)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.510	<.001	0.221 (0.163, 0.299)	77.91% (70.11%, 83.67%)
G9P[8]	Residence location (Urban vs Rural) ^[1]	0.165	0.314	1.180 (0.855, 1.627)	
	Regions of study hospitals (Central vs East) ^[1]	0.303	0.124	1.355 (0.921, 1.993)	
	Regions of study hospitals (West vs East) ^[1]	1.173	<.001	3.232 (2.314, 4.513)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.773	<.001	0.170 (0.108, 0.268)	83.02% (73.21%, 89.24%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.1.3, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 3: The 3rd sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, education level of the children's parents, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.3.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:1)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Birth seasons (RV peak season vs Non-RV peak season)	-0.405	0.530	0.667 (0.188, 2.362)
	Residence location (Urban vs Rural)	-0.511	0.484	0.600 (0.143, 2.511)
	Regions of study hospitals (Central vs East)	-0.468	0.633	0.626 (0.091, 4.288)
	Regions of study hospitals (West vs East)	-0.936	0.358	0.392 (0.053, 2.891)
	Clinical setting (Inpatient vs Outpatient)	1.099	0.341	3.000 (0.312, 28.841)
	Received ROTATEQ vaccination (Yes vs No)	-18.203	0.996	<0.001 (<0.001, >999.999)
G2	Birth seasons (RV peak season vs Non-RV peak season)	-0.262	0.533	0.769 (0.337, 1.754)
	Residence location (Urban vs Rural)	-0.693	0.090	0.500 (0.225, 1.113)
	Regions of study hospitals (Central vs East)	1.499	0.022	4.478 (1.236, 16.224)
	Regions of study hospitals (West vs East)	1.340	0.020	3.820 (1.237, 11.790)
	Clinical setting (Inpatient vs Outpatient)	0.318	0.493	1.375 (0.553, 3.418)
	Received ROTATEQ vaccination (Yes vs No)	-2.303	0.002	0.100 (0.023, 0.428)
G3	Birth seasons (RV peak season vs Non-RV peak season)	-0.159	0.374	0.853 (0.601, 1.211)
	Residence location (Urban vs Rural)	-0.390	0.046	0.677 (0.462, 0.992)
	Regions of study hospitals (Central vs East)	-0.216	0.340	0.806 (0.517, 1.256)
	Regions of study hospitals (West vs East)	-0.493	0.051	0.611 (0.372, 1.003)
	Clinical setting (Inpatient vs Outpatient)	0.780	0.032	2.182 (1.069, 4.454)
	Received ROTATEQ vaccination (Yes vs No)	-3.379	<.001	0.034 (0.011, 0.108)
G8	Birth seasons (RV peak season vs Non-RV peak season)	0.113	0.357	1.120 (0.880, 1.425)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

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Table 14.6.3.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G9	Residence location (Urban vs Rural)	-0.375	0.002	0.687 (0.540, 0.874)
	Regions of study hospitals (Central vs East)	0.289	0.042	1.335 (1.011, 1.762)
	Regions of study hospitals (West vs East)	-0.124	0.388	0.883 (0.666, 1.171)
	Clinical setting (Inpatient vs Outpatient)	1.000	<.001	2.719 (1.813, 4.077)
	Received ROTATEQ vaccination (Yes vs No)	-1.528	<.001	0.217 (0.151, 0.311)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.061	0.600	0.941 (0.749, 1.182)
	Residence location (Urban vs Rural)	-0.225	0.048	0.799 (0.639, 0.998)
	Regions of study hospitals (Central vs East)	0.502	<.001	1.653 (1.227, 2.226)
	Regions of study hospitals (West vs East)	0.925	<.001	2.521 (1.962, 3.240)
	Clinical setting (Inpatient vs Outpatient)	0.550	<.001	1.733 (1.305, 2.303)
P[4]	Received ROTATEQ vaccination (Yes vs No)	-1.859	<.001	0.156 (0.101, 0.240)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.435	0.261	0.647 (0.303, 1.381)
	Residence location (Urban vs Rural)	-0.194	0.591	0.824 (0.406, 1.671)
	Regions of study hospitals (Central vs East)	0.643	0.266	1.902 (0.613, 5.907)
	Regions of study hospitals (West vs East)	1.136	0.010	3.116 (1.312, 7.399)
	Clinical setting (Inpatient vs Outpatient)	0.693	0.166	2.000 (0.751, 5.329)
P[8]	Received ROTATEQ vaccination (Yes vs No)	-1.946	0.002	0.143 (0.043, 0.479)
	Birth seasons (RV peak season vs Non-RV peak season)	0.101	0.172	1.106 (0.957, 1.279)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

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Table 14.6.3.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1P[8]	Residence location (Urban vs Rural)	-0.296	<.001	0.744 (0.642, 0.862)
	Regions of study hospitals (Central vs East)	0.250	0.007	1.285 (1.071, 1.540)
	Regions of study hospitals (West vs East)	0.511	<.001	1.667 (1.403, 1.980)
	Clinical setting (Inpatient vs Outpatient)	0.552	<.001	1.737 (1.403, 2.150)
	Received ROTATEQ vaccination (Yes vs No)	-1.889	<.001	0.151 (0.118, 0.194)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.405	0.530	0.667 (0.188, 2.362)
	Residence location (Urban vs Rural)	-0.511	0.484	0.600 (0.143, 2.511)
	Regions of study hospitals (Central vs East)	-0.468	0.633	0.626 (0.091, 4.288)
	Regions of study hospitals (West vs East)	-0.936	0.358	0.392 (0.053, 2.891)
	Clinical setting (Inpatient vs Outpatient)	1.099	0.341	3.000 (0.312, 28.841)
G2P[4]	Received ROTATEQ vaccination (Yes vs No)	-18.203	0.996	<0.001 (<0.001, >999.999)
	Birth seasons (RV peak season vs Non-RV peak season)	-1.041	0.028	0.353 (0.139, 0.895)
	Residence location (Urban vs Rural)	-0.452	0.350	0.636 (0.247, 1.642)
	Regions of study hospitals (Central vs East)	0.268	0.655	1.307 (0.404, 4.234)
	Regions of study hospitals (West vs East)	1.227	0.020	3.412 (1.209, 9.629)
	Clinical setting (Inpatient vs Outpatient)	0.118	0.808	1.125 (0.434, 2.916)
G3P[8]	Received ROTATEQ vaccination (Yes vs No)	-2.079	0.050	0.125 (0.016, 0.999)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.047	0.790	0.954 (0.674, 1.351)
	Residence location (Urban vs Rural)	-0.639	0.001	0.528 (0.356, 0.782)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

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Table 14.6.3.1. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:1) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8P[8]	Regions of study hospitals (Central vs East)	-0.127	0.566	0.880 (0.570, 1.360)
	Regions of study hospitals (West vs East)	-0.481	0.054	0.618 (0.379, 1.007)
	Clinical setting (Inpatient vs Outpatient)	1.196	<.001	3.308 (1.779, 6.151)
	Received ROTATEQ vaccination (Yes vs No)	-2.773	<.001	0.063 (0.027, 0.143)
	Birth seasons (RV peak season vs Non-RV peak season)	0.093	0.455	1.098 (0.860, 1.401)
	Residence location (Urban vs Rural)	-0.303	0.015	0.739 (0.579, 0.942)
	Regions of study hospitals (Central vs East)	0.350	0.015	1.419 (1.070, 1.882)
	Regions of study hospitals (West vs East)	-0.004	0.977	0.996 (0.750, 1.323)
	Clinical setting (Inpatient vs Outpatient)	1.006	<.001	2.735 (1.847, 4.051)
	Received ROTATEQ vaccination (Yes vs No)	-1.438	<.001	0.237 (0.170, 0.332)
G9P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.013	0.908	1.013 (0.809, 1.270)
	Residence location (Urban vs Rural)	-0.316	0.005	0.729 (0.585, 0.908)
	Regions of study hospitals (Central vs East)	0.419	0.005	1.521 (1.132, 2.043)
	Regions of study hospitals (West vs East)	0.895	<.001	2.447 (1.897, 3.156)
	Clinical setting (Inpatient vs Outpatient)	0.503	<.001	1.654 (1.249, 2.191)
	Received ROTATEQ vaccination (Yes vs No)	-1.990	<.001	0.137 (0.088, 0.213)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

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Table 14.6.3.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:2)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Birth seasons (RV peak season vs Non-RV peak season)	0.107	0.850	1.113 (0.367, 3.375)
	Residence location (Urban vs Rural)	-0.658	0.263	0.518 (0.164, 1.639)
	Regions of study hospitals (Central vs East)	-0.060	0.942	0.941 (0.188, 4.723)
	Regions of study hospitals (West vs East)	-0.912	0.243	0.402 (0.087, 1.859)
	Clinical setting (Inpatient vs Outpatient)	-0.000	>.999	1.000 (0.156, 6.420)
	Received ROTATEQ vaccination (Yes vs No)	-18.112	0.995	<0.001 (<0.001, >999.999)
G2	Birth seasons (RV peak season vs Non-RV peak season)	*		
	Residence location (Urban vs Rural)	-0.334	0.316	0.716 (0.373, 1.375)
	Regions of study hospitals (Central vs East)	1.097	0.023	2.996 (1.165, 7.704)
	Regions of study hospitals (West vs East)	1.246	0.005	3.476 (1.446, 8.354)
	Clinical setting (Inpatient vs Outpatient)	0.175	0.678	1.191 (0.523, 2.712)
	Received ROTATEQ vaccination (Yes vs No)	-2.192	0.003	0.112 (0.026, 0.482)
G3	Birth seasons (RV peak season vs Non-RV peak season)	-0.115	0.455	0.891 (0.659, 1.205)
	Residence location (Urban vs Rural)	-0.387	0.020	0.679 (0.490, 0.942)
	Regions of study hospitals (Central vs East)	-0.056	0.782	0.946 (0.638, 1.401)
	Regions of study hospitals (West vs East)	-0.455	0.029	0.634 (0.421, 0.955)
	Clinical setting (Inpatient vs Outpatient)	1.125	<.001	3.081 (1.700, 5.584)
	Received ROTATEQ vaccination (Yes vs No)	-2.905	<.001	0.055 (0.025, 0.118)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

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Table 14.6.3.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:2) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8	Birth seasons (RV peak season vs Non-RV peak season)	0.065	0.544	1.067 (0.865, 1.317)
	Residence location (Urban vs Rural)	-0.345	0.001	0.708 (0.574, 0.874)
	Regions of study hospitals (Central vs East)	0.384	0.002	1.468 (1.157, 1.862)
	Regions of study hospitals (West vs East)	0.014	0.912	1.014 (0.793, 1.296)
	Clinical setting (Inpatient vs Outpatient)	0.983	<.001	2.672 (1.880, 3.798)
	Received ROTATEQ vaccination (Yes vs No)	-1.482	<.001	0.227 (0.168, 0.308)
G9	Birth seasons (RV peak season vs Non-RV peak season)	-0.021	0.843	0.979 (0.792, 1.210)
	Residence location (Urban vs Rural)	-0.256	0.013	0.774 (0.632, 0.948)
	Regions of study hospitals (Central vs East)	0.430	0.002	1.538 (1.176, 2.011)
	Regions of study hospitals (West vs East)	0.949	<.001	2.583 (2.063, 3.235)
	Clinical setting (Inpatient vs Outpatient)	0.472	<.001	1.604 (1.233, 2.086)
	Received ROTATEQ vaccination (Yes vs No)	-2.001	<.001	0.135 (0.091, 0.200)
P[4]	Birth seasons (RV peak season vs Non-RV peak season)	-0.590	0.080	0.554 (0.286, 1.074)
	Residence location (Urban vs Rural)	-0.211	0.513	0.810 (0.431, 1.523)
	Regions of study hospitals (Central vs East)	0.558	0.207	1.747 (0.735, 4.149)
	Regions of study hospitals (West vs East)	0.862	0.012	2.368 (1.210, 4.635)
	Clinical setting (Inpatient vs Outpatient)	0.635	0.147	1.887 (0.801, 4.448)
	Received ROTATEQ vaccination (Yes vs No)	-2.034	<.001	0.131 (0.045, 0.377)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

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Table 14.6.3.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:2) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.027	0.692	1.027 (0.899, 1.174)
	Residence location (Urban vs Rural)	-0.274	<.001	0.760 (0.666, 0.868)
	Regions of study hospitals (Central vs East)	0.238	0.004	1.269 (1.078, 1.493)
	Regions of study hospitals (West vs East)	0.455	<.001	1.577 (1.354, 1.836)
	Clinical setting (Inpatient vs Outpatient)	0.532	<.001	1.702 (1.399, 2.072)
	Received ROTATEQ vaccination (Yes vs No)	-1.945	<.001	0.143 (0.114, 0.180)
G1P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.107	0.850	1.113 (0.367, 3.375)
	Residence location (Urban vs Rural)	-0.658	0.263	0.518 (0.164, 1.639)
	Regions of study hospitals (Central vs East)	-0.060	0.942	0.941 (0.188, 4.723)
	Regions of study hospitals (West vs East)	-0.912	0.243	0.402 (0.087, 1.859)
	Clinical setting (Inpatient vs Outpatient)	-0.000	>.999	1.000 (0.156, 6.420)
	Received ROTATEQ vaccination (Yes vs No)	-18.112	0.995	<0.001 (<0.001, >999.999)
G2P[4]	Birth seasons (RV peak season vs Non-RV peak season)	-0.785	0.046	0.456 (0.211, 0.986)
	Residence location (Urban vs Rural)	*		
	Regions of study hospitals (Central vs East)	0.580	0.224	1.786 (0.702, 4.546)
	Regions of study hospitals (West vs East)	1.700	<.001	5.476 (2.157, 13.902)
	Clinical setting (Inpatient vs Outpatient)	*		
	Received ROTATEQ vaccination (Yes vs No)	-2.846	0.006	0.058 (0.008, 0.442)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

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Table 14.6.3.2. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:2) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G3P[8]	Birth seasons (RV peak season vs Non-RV peak season)	-0.008	0.958	0.992 (0.726, 1.355)
	Residence location (Urban vs Rural)	-0.493	0.003	0.611 (0.440, 0.847)
	Regions of study hospitals (Central vs East)	-0.049	0.805	0.952 (0.645, 1.405)
	Regions of study hospitals (West vs East)	-0.376	0.084	0.687 (0.449, 1.052)
	Clinical setting (Inpatient vs Outpatient)	1.181	<.001	3.258 (1.808, 5.870)
	Received ROTATEQ vaccination (Yes vs No)	-2.567	<.001	0.077 (0.040, 0.147)
G8P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.135	0.217	1.144 (0.924, 1.418)
	Residence location (Urban vs Rural)	-0.281	0.007	0.755 (0.615, 0.926)
	Regions of study hospitals (Central vs East)	0.269	0.027	1.309 (1.031, 1.661)
	Regions of study hospitals (West vs East)	-0.025	0.843	0.975 (0.763, 1.247)
	Clinical setting (Inpatient vs Outpatient)	0.920	<.001	2.509 (1.759, 3.579)
	Received ROTATEQ vaccination (Yes vs No)	-1.424	<.001	0.241 (0.179, 0.323)
G9P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.026	0.804	1.027 (0.833, 1.265)
	Residence location (Urban vs Rural)	-0.276	0.006	0.759 (0.622, 0.925)
	Regions of study hospitals (Central vs East)	0.390	0.004	1.476 (1.129, 1.930)
	Regions of study hospitals (West vs East)	1.010	<.001	2.745 (2.168, 3.475)
	Clinical setting (Inpatient vs Outpatient)	0.411	0.002	1.509 (1.158, 1.966)
	Received ROTATEQ vaccination (Yes vs No)	-1.982	<.001	0.138 (0.092, 0.205)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

* Results are not available due to the model convergence issue.

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Table 14.6.3.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:3)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Birth seasons (RV peak season vs Non-RV peak season)	-0.224	0.681	0.800 (0.276, 2.320)
	Residence location (Urban vs Rural)	-0.706	0.223	0.494 (0.159, 1.537)
	Regions of study hospitals (Central vs East)	-0.124	0.858	0.883 (0.226, 3.448)
	Regions of study hospitals (West vs East)	-0.842	0.253	0.431 (0.102, 1.826)
	Clinical setting (Inpatient vs Outpatient)	-0.203	0.819	0.816 (0.144, 4.627)
	Received ROTATEQ vaccination (Yes vs No)	-2.508	0.020	0.081 (0.010, 0.672)
G2	Birth seasons (RV peak season vs Non-RV peak season)	-0.567	0.091	0.567 (0.294, 1.095)
	Residence location (Urban vs Rural)	-0.442	0.157	0.643 (0.348, 1.186)
	Regions of study hospitals (Central vs East)	1.203	0.008	3.329 (1.372, 8.078)
	Regions of study hospitals (West vs East)	1.397	<.001	4.045 (1.771, 9.240)
	Clinical setting (Inpatient vs Outpatient)	0.086	0.837	1.089 (0.483, 2.458)
	Received ROTATEQ vaccination (Yes vs No)	-2.434	0.001	0.088 (0.020, 0.377)
G3	Birth seasons (RV peak season vs Non-RV peak season)	-0.162	0.285	0.850 (0.632, 1.145)
	Residence location (Urban vs Rural)	-0.312	0.045	0.732 (0.539, 0.994)
	Regions of study hospitals (Central vs East)	0.031	0.873	1.031 (0.708, 1.502)
	Regions of study hospitals (West vs East)	-0.489	0.016	0.614 (0.413, 0.911)
	Clinical setting (Inpatient vs Outpatient)	1.184	<.001	3.267 (1.836, 5.813)
	Received ROTATEQ vaccination (Yes vs No)	-2.861	<.001	0.057 (0.028, 0.118)
G8	Birth seasons (RV peak season vs Non-RV peak season)	0.131	0.202	1.140 (0.932, 1.394)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

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Table 14.6.3.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:3) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G9	Residence location (Urban vs Rural)	-0.334	<.001	0.716 (0.589, 0.869)
	Regions of study hospitals (Central vs East)	0.348	0.002	1.416 (1.133, 1.768)
	Regions of study hospitals (West vs East)	-0.008	0.942	0.992 (0.788, 1.248)
	Clinical setting (Inpatient vs Outpatient)	0.971	<.001	2.640 (1.889, 3.689)
	Received ROTATEQ vaccination (Yes vs No)	-1.508	<.001	0.221 (0.166, 0.295)
	Birth seasons (RV peak season vs Non-RV peak season)	0.012	0.910	1.012 (0.824, 1.243)
	Residence location (Urban vs Rural)	-0.221	0.027	0.802 (0.660, 0.975)
	Regions of study hospitals (Central vs East)	0.435	0.001	1.544 (1.190, 2.004)
	Regions of study hospitals (West vs East)	0.984	<.001	2.676 (2.151, 3.328)
	Clinical setting (Inpatient vs Outpatient)	0.459	<.001	1.582 (1.219, 2.054)
P[4]	Received ROTATEQ vaccination (Yes vs No)	-2.057	<.001	0.128 (0.087, 0.187)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.594	0.057	0.552 (0.300, 1.017)
	Residence location (Urban vs Rural)	-0.294	0.321	0.745 (0.416, 1.333)
	Regions of study hospitals (Central vs East)	0.523	0.186	1.686 (0.777, 3.658)
	Regions of study hospitals (West vs East)	1.028	0.003	2.795 (1.423, 5.491)
	Clinical setting (Inpatient vs Outpatient)	0.588	0.132	1.800 (0.837, 3.870)
P[8]	Received ROTATEQ vaccination (Yes vs No)	-2.207	<.001	0.110 (0.038, 0.315)
	Birth seasons (RV peak season vs Non-RV peak season)	0.028	0.679	1.028 (0.903, 1.171)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

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Table 14.6.3.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:3) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1P[8]	Residence location (Urban vs Rural)	-0.249	<.001	0.779 (0.685, 0.887)
	Regions of study hospitals (Central vs East)	0.253	0.002	1.288 (1.098, 1.511)
	Regions of study hospitals (West vs East)	0.452	<.001	1.571 (1.355, 1.821)
	Clinical setting (Inpatient vs Outpatient)	0.512	<.001	1.668 (1.373, 2.026)
	Received ROTATEQ vaccination (Yes vs No)	-1.931	<.001	0.145 (0.117, 0.180)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.224	0.681	0.800 (0.276, 2.320)
	Residence location (Urban vs Rural)	-0.706	0.223	0.494 (0.159, 1.537)
	Regions of study hospitals (Central vs East)	-0.124	0.858	0.883 (0.226, 3.448)
	Regions of study hospitals (West vs East)	-0.842	0.253	0.431 (0.102, 1.826)
	Clinical setting (Inpatient vs Outpatient)	-0.203	0.819	0.816 (0.144, 4.627)
G2P[4]	Received ROTATEQ vaccination (Yes vs No)	-2.508	0.020	0.081 (0.010, 0.672)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.709	0.043	0.492 (0.248, 0.976)
	Residence location (Urban vs Rural)	-0.559	0.100	0.572 (0.294, 1.113)
	Regions of study hospitals (Central vs East)	0.983	0.037	2.671 (1.059, 6.736)
	Regions of study hospitals (West vs East)	1.782	<.001	5.943 (2.429, 14.543)
	Clinical setting (Inpatient vs Outpatient)	0.044	0.917	1.045 (0.458, 2.387)
G3P[8]	Received ROTATEQ vaccination (Yes vs No)	-2.975	0.004	0.051 (0.007, 0.382)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.079	0.612	0.924 (0.681, 1.254)
	Residence location (Urban vs Rural)	-0.395	0.012	0.674 (0.495, 0.917)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

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Table 14.6.3.3. Conditional Univariate Logistic Regression (By G-type, P-type and G/P type combinations-Sensitivity analysis 4-1:3) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8P[8]	Regions of study hospitals (Central vs East)	0.012	0.950	1.012 (0.692, 1.481)
	Regions of study hospitals (West vs East)	-0.440	0.033	0.644 (0.430, 0.966)
	Clinical setting (Inpatient vs Outpatient)	1.118	<.001	3.058 (1.714, 5.455)
	Received ROTATEQ vaccination (Yes vs No)	-2.581	<.001	0.076 (0.041, 0.141)
	Birth seasons (RV peak season vs Non-RV peak season)	0.117	0.247	1.124 (0.922, 1.371)
	Residence location (Urban vs Rural)	-0.272	0.006	0.761 (0.628, 0.923)
	Regions of study hospitals (Central vs East)	0.287	0.012	1.332 (1.064, 1.668)
	Regions of study hospitals (West vs East)	0.004	0.971	1.004 (0.795, 1.269)
	Clinical setting (Inpatient vs Outpatient)	0.890	<.001	2.434 (1.739, 3.408)
	Received ROTATEQ vaccination (Yes vs No)	-1.484	<.001	0.227 (0.170, 0.302)
G9P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.054	0.599	1.056 (0.862, 1.293)
	Residence location (Urban vs Rural)	-0.210	0.033	0.811 (0.668, 0.983)
	Regions of study hospitals (Central vs East)	0.383	0.004	1.466 (1.131, 1.902)
	Regions of study hospitals (West vs East)	1.057	<.001	2.879 (2.293, 3.615)
	Clinical setting (Inpatient vs Outpatient)	0.394	0.003	1.483 (1.143, 1.923)
	Received ROTATEQ vaccination (Yes vs No)	-1.990	<.001	0.137 (0.093, 0.200)

Dependent variable (Case Group vs Control Group). Conditional univariate logistic regression was used.

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

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Table 14.6.4.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 4-1:1)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	NA	NA	NA	NA	NA
G2	Residence location (Urban vs Rural) ^[1]	-0.996	0.076	0.369 (0.123, 1.110)	
	Regions of study hospitals (Central vs East) ^[1]	1.790	0.037	5.992 (1.111, 32.309)	
	Regions of study hospitals (West vs East) ^[1]	2.072	0.009	7.944 (1.680, 37.563)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.643	0.002	0.071 (0.014, 0.374)	92.88% (62.57%, 98.65%)
G3	Residence location (Urban vs Rural) ^[1]	-0.248	0.308	0.780 (0.484, 1.257)	
	Regions of study hospitals (Central vs East) ^[1]	-0.207	0.478	0.813 (0.460, 1.439)	
	Regions of study hospitals (West vs East) ^[1]	0.010	0.973	1.011 (0.547, 1.867)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.624	0.143	1.866 (0.810, 4.302)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.347	<.001	0.035 (0.011, 0.112)	96.48% (88.81%, 98.89%)
G8	Residence location (Urban vs Rural) ^[1]	-0.276	0.041	0.759 (0.583, 0.989)	
	Regions of study hospitals (Central vs East) ^[1]	0.144	0.349	1.155 (0.855, 1.560)	
	Regions of study hospitals (West vs East) ^[1]	-0.051	0.747	0.950 (0.695, 1.298)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.850	<.001	2.339 (1.520, 3.601)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.448	<.001	0.235 (0.163, 0.339)	76.50% (66.11%, 83.71%)
G9	Residence location (Urban vs Rural) ^[1]	-0.196	0.141	0.822 (0.633, 1.067)	
	Regions of study hospitals (Central vs East) ^[1]	0.256	0.128	1.292 (0.929, 1.797)	
	Regions of study hospitals (West vs East) ^[1]	1.063	<.001	2.895 (2.177, 3.849)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.739	<.001	2.093 (1.482, 2.956)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.863	<.001	0.155 (0.098, 0.245)	84.47% (75.53%, 90.15%)
P[4]	Regions of study hospitals (Central vs East) ^[1]	0.644	0.336	1.905 (0.513, 7.072)	
	Regions of study hospitals (West vs East) ^[1]	1.191	0.013	3.290 (1.286, 8.417)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.992	0.002	0.136 (0.039, 0.475)	86.36% (52.53%, 96.08%)
P[8]	Residence location (Urban vs Rural) ^[1]	-0.291	<.001	0.748 (0.631, 0.887)	
	Regions of study hospitals (Central vs East) ^[1]	0.128	0.222	1.136 (0.926, 1.395)	

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.3.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

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Table 14.6.4.1. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 4-1:1) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
	Regions of study hospitals (West vs East) ^[1]	0.611	<.001	1.842 (1.507, 2.252)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.601	<.001	1.825 (1.424, 2.337)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.872	<.001	0.154 (0.119, 0.199)	84.62% (80.12%, 88.10%)
G1P[8]	NA	NA	NA	NA	NA
G2P[4]	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-1.522	0.027	0.218 (0.057, 0.840)	
	Regions of study hospitals (Central vs East) ^[1]	0.509	0.536	1.664 (0.331, 8.371)	
	Regions of study hospitals (West vs East) ^[1]	2.026	0.009	7.581 (1.666, 34.494)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.597	0.010	0.027 (0.002, 0.420)	97.26% (58.04%, 99.82%)
G3P[8]	Residence location (Urban vs Rural) ^[1]	-0.471	0.048	0.624 (0.391, 0.996)	
	Regions of study hospitals (Central vs East) ^[1]	0.051	0.860	1.053 (0.594, 1.866)	
	Regions of study hospitals (West vs East) ^[1]	-0.144	0.639	0.865 (0.473, 1.583)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.731	0.045	2.076 (1.018, 4.236)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.669	<.001	0.069 (0.030, 0.160)	93.07% (84.02%, 96.99%)
G8P[8]	Residence location (Urban vs Rural) ^[1]	-0.198	0.150	0.821 (0.627, 1.074)	
	Regions of study hospitals (Central vs East) ^[1]	0.169	0.283	1.184 (0.870, 1.610)	
	Regions of study hospitals (West vs East) ^[1]	0.105	0.517	1.111 (0.808, 1.526)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.908	<.001	2.478 (1.616, 3.801)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.395	<.001	0.248 (0.176, 0.349)	75.20% (65.07%, 82.40%)
G9P[8]	Residence location (Urban vs Rural) ^[1]	-0.260	0.049	0.771 (0.596, 0.999)	
	Regions of study hospitals (Central vs East) ^[1]	0.172	0.310	1.188 (0.852, 1.656)	
	Regions of study hospitals (West vs East) ^[1]	0.959	<.001	2.610 (1.948, 3.495)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.765	<.001	2.149 (1.516, 3.047)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.963	<.001	0.140 (0.088, 0.225)	85.95% (77.50%, 91.23%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.3.1, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

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Table 14.6.4.2. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 4-1:2)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	NA	NA	NA	NA	NA
G2	Regions of study hospitals (Central vs East) ^[1]	1.018	0.055	2.766 (0.980, 7.810)	91.09% (58.43%, 98.09%)
	Regions of study hospitals (West vs East) ^[1]	1.517	0.003	4.557 (1.698, 12.230)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.418	0.002	0.089 (0.019, 0.416)	
G3	Residence location (Urban vs Rural) ^[1]	-0.086	0.656	0.917 (0.627, 1.342)	94.23% (87.43%, 97.35%)
	Regions of study hospitals (Central vs East) ^[1]	-0.235	0.318	0.790 (0.498, 1.254)	
	Regions of study hospitals (West vs East) ^[1]	-0.313	0.189	0.731 (0.458, 1.166)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.009	0.003	2.742 (1.402, 5.363)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.852	<.001	0.058 (0.026, 0.126)	
G8	Residence location (Urban vs Rural) ^[1]	-0.254	0.026	0.776 (0.620, 0.970)	75.73% (67.05%, 82.13%)
	Regions of study hospitals (Central vs East) ^[1]	0.213	0.098	1.237 (0.962, 1.591)	
	Regions of study hospitals (West vs East) ^[1]	0.094	0.492	1.098 (0.841, 1.435)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.894	<.001	2.445 (1.682, 3.553)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.416	<.001	0.243 (0.179, 0.330)	
G9	Residence location (Urban vs Rural) ^[1]	-0.244	0.040	0.783 (0.620, 0.989)	85.88% (78.82%, 90.59%)
	Regions of study hospitals (Central vs East) ^[1]	0.250	0.094	1.284 (0.958, 1.720)	
	Regions of study hospitals (West vs East) ^[1]	1.076	<.001	2.933 (2.277, 3.777)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.681	<.001	1.975 (1.444, 2.702)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.958	<.001	0.141 (0.094, 0.212)	
P[4]	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.542	0.150	0.582 (0.278, 1.217)	85.95% (59.26%, 95.15%)
	Regions of study hospitals (Central vs East) ^[1]	0.583	0.222	1.792 (0.703, 4.566)	
	Regions of study hospitals (West vs East) ^[1]	0.709	0.053	2.032 (0.990, 4.169)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.962	<.001	0.141 (0.048, 0.407)	
P[8]	Residence location (Urban vs Rural) ^[1]	-0.237	0.002	0.789 (0.681, 0.914)	85.95% (59.26%, 95.15%)
	Regions of study hospitals (Central vs East) ^[1]	0.151	0.095	1.163 (0.974, 1.389)	

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.3.2, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

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Table 14.6.4.2. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 4-1:2) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
	Regions of study hospitals (West vs East) ^[1]	0.525	<.001	1.690 (1.426, 2.003)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.496	<.001	1.642 (1.322, 2.040)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.923	<.001	0.146 (0.116, 0.184)	85.39% (81.59%, 88.40%)
G1P[8]	NA	NA	NA	NA	NA
G2P[4]	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.816	0.084	0.442 (0.175, 1.117)	
	Regions of study hospitals (Central vs East) ^[1]	0.657	0.260	1.929 (0.615, 6.047)	
	Regions of study hospitals (West vs East) ^[1]	1.906	0.001	6.725 (2.159, 20.951)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-3.636	0.003	0.026 (0.002, 0.287)	97.36% (71.27%, 99.76%)
G3P[8]	Residence location (Urban vs Rural) ^[1]	-0.408	0.039	0.665 (0.451, 0.980)	
	Regions of study hospitals (Central vs East) ^[1]	-0.100	0.664	0.905 (0.576, 1.421)	
	Regions of study hospitals (West vs East) ^[1]	-0.081	0.747	0.922 (0.563, 1.510)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.838	0.010	2.312 (1.227, 4.356)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.488	<.001	0.083 (0.043, 0.161)	91.69% (83.91%, 95.71%)
G8P[8]	Residence location (Urban vs Rural) ^[1]	-0.164	0.141	0.849 (0.683, 1.056)	
	Regions of study hospitals (Central vs East) ^[1]	0.157	0.221	1.170 (0.910, 1.505)	
	Regions of study hospitals (West vs East) ^[1]	0.116	0.394	1.123 (0.860, 1.465)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.822	<.001	2.275 (1.571, 3.295)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.376	<.001	0.253 (0.188, 0.340)	74.74% (65.97%, 81.24%)
G9P[8]	Residence location (Urban vs Rural) ^[1]	-0.272	0.018	0.762 (0.608, 0.954)	
	Regions of study hospitals (Central vs East) ^[1]	0.237	0.110	1.268 (0.947, 1.697)	
	Regions of study hospitals (West vs East) ^[1]	1.048	<.001	2.853 (2.203, 3.695)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.612	<.001	1.844 (1.348, 2.522)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.931	<.001	0.145 (0.096, 0.220)	85.50% (78.02%, 90.43%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.3.2, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

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Table 14.6.4.3. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 4-1:3)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.508	0.020	0.081 (0.010, 0.672)	91.86% (32.79%, 99.01%)
G2	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.359	0.351	0.698 (0.328, 1.485)	93.27% (67.26%, 98.62%)
	Regions of study hospitals (Central vs East) ^[1]	1.141	0.021	3.128 (1.191, 8.220)	
	Regions of study hospitals (West vs East) ^[1]	1.679	<.001	5.362 (2.113, 13.608)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.698	<.001	0.067 (0.014, 0.327)	
G3	Residence location (Urban vs Rural) ^[1]	-0.013	0.943	0.987 (0.694, 1.404)	94.12% (87.71%, 97.18%)
	Regions of study hospitals (Central vs East) ^[1]	-0.182	0.409	0.834 (0.541, 1.284)	
	Regions of study hospitals (West vs East) ^[1]	-0.467	0.035	0.627 (0.406, 0.968)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.078	<.001	2.939 (1.548, 5.581)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.833	<.001	0.059 (0.028, 0.123)	
G8	Residence location (Urban vs Rural) ^[1]	-0.232	0.029	0.793 (0.644, 0.976)	76.53% (68.72%, 82.39%)
	Regions of study hospitals (Central vs East) ^[1]	0.237	0.047	1.268 (1.003, 1.602)	
	Regions of study hospitals (West vs East) ^[1]	0.103	0.411	1.108 (0.868, 1.415)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.857	<.001	2.355 (1.653, 3.357)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.450	<.001	0.235 (0.176, 0.313)	
G9	Residence location (Urban vs Rural) ^[1]	-0.179	0.112	0.836 (0.671, 1.042)	86.67% (80.28%, 90.98%)
	Regions of study hospitals (Central vs East) ^[1]	0.281	0.051	1.324 (0.999, 1.756)	
	Regions of study hospitals (West vs East) ^[1]	1.102	<.001	3.011 (2.361, 3.839)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.671	<.001	1.956 (1.440, 2.658)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.015	<.001	0.133 (0.090, 0.197)	
P[4]	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.557	0.111	0.573 (0.289, 1.136)	88.08% (65.93%, 95.83%)
	Regions of study hospitals (Central vs East) ^[1]	0.530	0.207	1.699 (0.745, 3.875)	
	Regions of study hospitals (West vs East) ^[1]	0.834	0.026	2.303 (1.106, 4.796)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.127	<.001	0.119 (0.042, 0.341)	
P[8]	Residence location (Urban vs Rural) ^[1]	-0.183	0.011	0.832 (0.722, 0.959)	

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.3.3, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

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Table 14.6.4.3. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 4-1:3) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
	Regions of study hospitals (Central vs East) ^[1]	0.167	0.057	1.182 (0.995, 1.404)	
	Regions of study hospitals (West vs East) ^[1]	0.508	<.001	1.662 (1.411, 1.956)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.485	<.001	1.625 (1.312, 2.012)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.911	<.001	0.148 (0.119, 0.184)	85.21% (81.57%, 88.13%)
G1P[8]	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.508	0.020	0.081 (0.010, 0.672)	91.86% (32.79%, 99.01%)
G2P[4]	Birth seasons (RV peak season vs Non-RV peak season) ^[1]	-0.456	0.255	0.634 (0.289, 1.389)	
	Residence location (Urban vs Rural) ^[1]	-0.708	0.119	0.493 (0.202, 1.200)	
	Regions of study hospitals (Central vs East) ^[1]	0.634	0.231	1.885 (0.668, 5.317)	
	Regions of study hospitals (West vs East) ^[1]	1.692	<.001	5.432 (2.013, 14.662)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.901	0.007	0.055 (0.007, 0.445)	94.50% (55.53%, 99.32%)
G3P[8]	Residence location (Urban vs Rural) ^[1]	-0.273	0.136	0.761 (0.532, 1.089)	
	Regions of study hospitals (Central vs East) ^[1]	-0.100	0.652	0.905 (0.586, 1.397)	
	Regions of study hospitals (West vs East) ^[1]	-0.299	0.199	0.742 (0.471, 1.170)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.816	0.009	2.262 (1.222, 4.189)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.511	<.001	0.081 (0.043, 0.153)	91.88% (84.70%, 95.69%)
G8P[8]	Residence location (Urban vs Rural) ^[1]	-0.139	0.181	0.870 (0.710, 1.067)	
	Regions of study hospitals (Central vs East) ^[1]	0.202	0.094	1.224 (0.966, 1.550)	
	Regions of study hospitals (West vs East) ^[1]	0.137	0.274	1.147 (0.897, 1.468)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.802	<.001	2.230 (1.567, 3.174)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.446	<.001	0.235 (0.176, 0.314)	76.46% (68.58%, 82.36%)
G9P[8]	Residence location (Urban vs Rural) ^[1]	-0.212	0.056	0.809 (0.651, 1.005)	
	Regions of study hospitals (Central vs East) ^[1]	0.239	0.092	1.270 (0.962, 1.676)	
	Regions of study hospitals (West vs East) ^[1]	1.106	<.001	3.022 (2.360, 3.869)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.620	<.001	1.859 (1.376, 2.513)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.956	<.001	0.141 (0.095, 0.210)	85.86% (79.02%, 90.47%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.3.3, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 4: The 4th sensitivity analysis will be performed based on the children who have complete data for all matching factors above (age of onset (in months), gender, symptom onset season).

1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1	Age of onset (in months) (Continuous)	0.016	0.327	1.016 (0.984, 1.050)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.220	0.652	0.803 (0.309, 2.085)
	Residence location (Urban vs Rural)	-1.240	0.015	0.289 (0.107, 0.784)
	Regions of study hospitals (Central vs East)	0.104	0.853	1.109 (0.371, 3.319)
	Regions of study hospitals (West vs East)	-0.409	0.540	0.664 (0.179, 2.459)
	Clinical setting (Inpatient vs Outpatient)	0.088	0.908	1.092 (0.249, 4.788)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.000	>.999	1.000 (0.322, 3.109)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.214	0.724	0.807 (0.246, 2.651)
	Gender (Male vs Female)	1.135	0.075	3.110 (0.892, 10.837)
	College and above for either parent's education level (Yes vs No)	-0.785	0.107	0.456 (0.176, 1.186)
G2	Received ROTATEQ vaccination (Yes vs No)	-2.293	0.026	0.101 (0.013, 0.763)
	Age of onset (in months) (Continuous)	0.007	0.600	1.007 (0.981, 1.034)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.402	0.265	0.669 (0.330, 1.357)
	Residence location (Urban vs Rural)	-0.175	0.637	0.840 (0.406, 1.735)
	Regions of study hospitals (Central vs East)	0.943	0.062	2.567 (0.953, 6.915)
	Regions of study hospitals (West vs East)	1.452	0.002	4.270 (1.735, 10.508)
	Clinical setting (Inpatient vs Outpatient)	1.474	0.148	4.366 (0.594, 32.088)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.000	>.999	1.000 (0.374, 2.673)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G3	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	0.596	0.175	1.816 (0.767, 4.298)
	Gender (Male vs Female)	0.192	0.610	1.212 (0.579, 2.537)
	College and above for either parent's education level (Yes vs No)	-0.443	0.232	0.642 (0.311, 1.328)
	Received ROTATEQ vaccination (Yes vs No)	-2.921	0.004	0.054 (0.007, 0.395)
	Age of onset (in months) (Continuous)	0.054	<.001	1.056 (1.048, 1.064)
	Birth seasons (RV peak season vs Non-RV peak season)	0.019	0.888	1.019 (0.781, 1.330)
	Residence location (Urban vs Rural)	-0.371	0.006	0.690 (0.529, 0.900)
	Regions of study hospitals (Central vs East)	-0.407	0.015	0.666 (0.479, 0.925)
	Regions of study hospitals (West vs East)	-0.684	<.001	0.505 (0.351, 0.727)
	Clinical setting (Inpatient vs Outpatient)	0.924	0.001	2.518 (1.428, 4.441)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-3.602	<.001	0.027 (0.012, 0.062)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-2.941	<.001	0.053 (0.029, 0.095)
	Gender (Male vs Female)	0.146	0.293	1.157 (0.882, 1.519)
	College and above for either parent's education level (Yes vs No)	-0.351	0.012	0.704 (0.536, 0.925)
	Received ROTATEQ vaccination (Yes vs No)	-2.547	<.001	0.078 (0.043, 0.144)
G8	Age of onset (in months) (Continuous)	0.030	<.001	1.031 (1.025, 1.037)
	Birth seasons (RV peak season vs Non-RV peak season)	0.015	0.872	1.015 (0.848, 1.215)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G9	Residence location (Urban vs Rural)	-0.245	0.008	0.783 (0.653, 0.938)
	Regions of study hospitals (Central vs East)	0.335	0.002	1.398 (1.135, 1.722)
	Regions of study hospitals (West vs East)	0.088	0.439	1.092 (0.874, 1.364)
	Clinical setting (Inpatient vs Outpatient)	0.642	<.001	1.899 (1.358, 2.657)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	1.069	<.001	2.912 (2.321, 3.655)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.015	0.915	0.985 (0.752, 1.291)
	Gender (Male vs Female)	0.096	0.304	1.101 (0.917, 1.321)
	College and above for either parent's education level (Yes vs No)	-0.409	<.001	0.664 (0.552, 0.799)
	Received ROTATEQ vaccination (Yes vs No)	-1.644	<.001	0.193 (0.147, 0.255)
	Age of onset (in months) (Continuous)	0.029	<.001	1.029 (1.022, 1.037)
	Birth seasons (RV peak season vs Non-RV peak season)	0.018	0.883	1.018 (0.805, 1.287)
	Residence location (Urban vs Rural)	0.222	0.084	1.249 (0.971, 1.606)
	Regions of study hospitals (Central vs East)	0.160	0.352	1.173 (0.838, 1.643)
	Regions of study hospitals (West vs East)	1.184	<.001	3.266 (2.507, 4.255)
	Clinical setting (Inpatient vs Outpatient)	0.022	0.901	1.022 (0.721, 1.449)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.008	0.951	0.992 (0.762, 1.291)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.588	<.001	0.556 (0.410, 0.753)
	Gender (Male vs Female)	0.193	0.116	1.213 (0.954, 1.543)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
P[4]	College and above for either parent's education level (Yes vs No)	-0.057	0.660	0.945 (0.735, 1.216)
	Received ROTATEQ vaccination (Yes vs No)	-1.764	<.001	0.171 (0.117, 0.251)
	Age of onset (in months) (Continuous)	0.022	0.033	1.022 (1.002, 1.043)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.338	0.288	0.713 (0.383, 1.331)
	Residence location (Urban vs Rural)	-0.015	0.963	0.985 (0.512, 1.892)
	Regions of study hospitals (Central vs East)	0.063	0.886	1.065 (0.450, 2.521)
	Regions of study hospitals (West vs East)	0.815	0.022	2.258 (1.123, 4.542)
	Clinical setting (Inpatient vs Outpatient)	1.736	0.087	5.674 (0.778, 41.375)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.405	0.443	1.499 (0.532, 4.225)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	1.395	0.002	4.034 (1.650, 9.867)
	Gender (Male vs Female)	-0.205	0.522	0.815 (0.436, 1.524)
	College and above for either parent's education level (Yes vs No)	-0.055	0.874	0.946 (0.479, 1.868)
	Received ROTATEQ vaccination (Yes vs No)	-2.464	<.001	0.085 (0.020, 0.353)
	Age of onset (in months) (Continuous)	0.037	<.001	1.038 (1.033, 1.042)
P[8]	Birth seasons (RV peak season vs Non-RV peak season)	0.014	0.837	1.014 (0.886, 1.161)
	Residence location (Urban vs Rural)	-0.144	0.041	0.866 (0.754, 0.994)
	Regions of study hospitals (Central vs East)	0.135	0.110	1.144 (0.970, 1.350)
	Regions of study hospitals (West vs East)	0.309	<.001	1.362 (1.162, 1.596)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G1P[8]	Clinical setting (Inpatient vs Outpatient)	0.457	<.001	1.580 (1.253, 1.991)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.002	0.978	1.002 (0.862, 1.165)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.914	<.001	0.401 (0.333, 0.483)
	Gender (Male vs Female)	0.137	0.052	1.147 (0.999, 1.316)
	College and above for either parent's education level (Yes vs No)	-0.322	<.001	0.725 (0.630, 0.835)
	Received ROTATEQ vaccination (Yes vs No)	-1.826	<.001	0.161 (0.130, 0.199)
	Age of onset (in months) (Continuous)	0.016	0.327	1.016 (0.984, 1.050)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.220	0.652	0.803 (0.309, 2.085)
	Residence location (Urban vs Rural)	-1.240	0.015	0.289 (0.107, 0.784)
	Regions of study hospitals (Central vs East)	0.104	0.853	1.109 (0.371, 3.319)
	Regions of study hospitals (West vs East)	-0.409	0.540	0.664 (0.179, 2.459)
	Clinical setting (Inpatient vs Outpatient)	0.088	0.908	1.092 (0.249, 4.788)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.000	>.999	1.000 (0.322, 3.109)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.214	0.724	0.807 (0.246, 2.651)
	Gender (Male vs Female)	1.135	0.075	3.110 (0.892, 10.837)
	College and above for either parent's education level (Yes vs No)	-0.785	0.107	0.456 (0.176, 1.186)
	Received ROTATEQ vaccination (Yes vs No)	-2.293	0.026	0.101 (0.013, 0.763)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G2P[4]	Age of onset (in months) (Continuous)	0.008	0.590	1.008 (0.980, 1.036)
	Birth seasons (RV peak season vs Non-RV peak season)	-0.269	0.472	0.764 (0.368, 1.588)
	Residence location (Urban vs Rural)	0.008	0.985	1.008 (0.467, 2.173)
	Regions of study hospitals (Central vs East)	0.979	0.071	2.662 (0.921, 7.696)
	Regions of study hospitals (West vs East)	1.606	<.001	4.981 (1.926, 12.880)
	Clinical setting (Inpatient vs Outpatient)	1.405	0.168	4.075 (0.553, 30.020)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	0.288	0.595	1.333 (0.461, 3.854)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	0.884	0.068	2.421 (0.936, 6.260)
	Gender (Male vs Female)	0.236	0.547	1.267 (0.587, 2.732)
	College and above for either parent's education level (Yes vs No)	-0.261	0.506	0.771 (0.357, 1.662)
	Received ROTATEQ vaccination (Yes vs No)	-2.852	0.005	0.058 (0.008, 0.425)
G3P[8]	Age of onset (in months) (Continuous)	0.054	<.001	1.056 (1.048, 1.063)
	Birth seasons (RV peak season vs Non-RV peak season)	0.064	0.641	1.067 (0.814, 1.398)
	Residence location (Urban vs Rural)	-0.347	0.012	0.707 (0.540, 0.925)
	Regions of study hospitals (Central vs East)	-0.400	0.018	0.670 (0.480, 0.935)
	Regions of study hospitals (West vs East)	-0.683	<.001	0.505 (0.349, 0.730)
	Clinical setting (Inpatient vs Outpatient)	0.897	0.002	2.451 (1.389, 4.324)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-4.286	<.001	0.014 (0.004, 0.043)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
G8P[8]	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-3.019	<.001	0.049 (0.027, 0.090)
	Gender (Male vs Female)	0.124	0.377	1.132 (0.860, 1.489)
	College and above for either parent's education level (Yes vs No)	-0.336	0.017	0.714 (0.542, 0.942)
	Received ROTATEQ vaccination (Yes vs No)	-2.520	<.001	0.080 (0.044, 0.148)
	Age of onset (in months) (Continuous)	0.030	<.001	1.031 (1.025, 1.037)
	Birth seasons (RV peak season vs Non-RV peak season)	0.013	0.887	1.013 (0.846, 1.214)
	Residence location (Urban vs Rural)	-0.239	0.010	0.787 (0.656, 0.944)
	Regions of study hospitals (Central vs East)	0.327	0.002	1.387 (1.125, 1.711)
	Regions of study hospitals (West vs East)	0.092	0.419	1.096 (0.877, 1.370)
	Clinical setting (Inpatient vs Outpatient)	0.636	<.001	1.888 (1.350, 2.642)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	1.072	<.001	2.920 (2.325, 3.668)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.006	0.966	0.994 (0.758, 1.303)
	Gender (Male vs Female)	0.095	0.310	1.100 (0.915, 1.321)
	College and above for either parent's education level (Yes vs No)	-0.402	<.001	0.669 (0.556, 0.805)
	Received ROTATEQ vaccination (Yes vs No)	-1.657	<.001	0.191 (0.144, 0.252)
G9P[8]	Age of onset (in months) (Continuous)	0.027	<.001	1.028 (1.020, 1.036)
	Birth seasons (RV peak season vs Non-RV peak season)	0.038	0.757	1.038 (0.818, 1.318)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.5. Univariate Logistic Regression-By G-type, P-type and G/P type combinations (Secondary Endpoint-Sensitivity analysis 5) (Continued)

<i>Types</i>	<i>Factors</i>	<i>Regression Coefficient</i>	<i>P Value</i>	<i>OR (95% CI)</i>
	Residence location (Urban vs Rural)	0.234	0.074	1.263 (0.977, 1.633)
	Regions of study hospitals (Central vs East)	0.257	0.141	1.293 (0.918, 1.821)
	Regions of study hospitals (West vs East)	1.268	<.001	3.555 (2.707, 4.670)
	Clinical setting (Inpatient vs Outpatient)	-0.019	0.916	0.981 (0.692, 1.392)
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.000	>.999	1.000 (0.768, 1.302)
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.734	<.001	0.480 (0.349, 0.661)
	Gender (Male vs Female)	0.238	0.058	1.269 (0.992, 1.624)
	College and above for either parent's education level (Yes vs No)	-0.093	0.475	0.912 (0.707, 1.176)
	Received ROTATEQ vaccination (Yes vs No)	-1.762	<.001	0.172 (0.116, 0.253)

Dependent variable (Case Group vs Control Group). Unconditional univariate logistic regression was used.

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

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Table 14.6.6. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 5)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G1	Residence location (Urban vs Rural) ^[1]	-1.138	0.026	0.320 (0.118, 0.870)	
	Gender (Male vs Female) ^[1]	1.110	0.082	3.034 (0.869, 10.593)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.177	0.035	0.113 (0.015, 0.858)	88.66% (14.18%, 98.50%)
G2	Regions of study hospitals (Central vs East) ^[1]	0.886	0.080	2.427 (0.899, 6.546)	
	Regions of study hospitals (West vs East) ^[1]	1.436	0.002	4.203 (1.705, 10.363)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.905	0.004	0.055 (0.007, 0.402)	94.52% (59.81%, 99.25%)
G3	Age of onset (in months) (Continuous) ^[1]	0.038	<.001	1.038 (1.030, 1.047)	
	Residence location (Urban vs Rural) ^[1]	-0.119	0.465	0.888 (0.646, 1.220)	
	Regions of study hospitals (Central vs East) ^[1]	-0.208	0.280	0.812 (0.556, 1.185)	
	Regions of study hospitals (West vs East) ^[1]	-0.327	0.119	0.721 (0.478, 1.088)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.015	0.002	2.760 (1.472, 5.174)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	-3.397	<.001	0.033 (0.015, 0.076)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-2.791	<.001	0.061 (0.033, 0.114)	
	College and above for either parent's education level (Yes vs No) ^[1]	-0.235	0.161	0.790 (0.569, 1.098)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.491	<.001	0.083 (0.044, 0.155)	91.72% (84.54%, 95.56%)
G8	Age of onset (in months) (Continuous) ^[1]	0.044	<.001	1.045 (1.037, 1.052)	
	Residence location (Urban vs Rural) ^[1]	-0.245	0.018	0.782 (0.639, 0.958)	
	Regions of study hospitals (Central vs East) ^[1]	0.368	0.001	1.445 (1.154, 1.810)	
	Regions of study hospitals (West vs East) ^[1]	0.179	0.144	1.196 (0.941, 1.522)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.687	<.001	1.987 (1.391, 2.838)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	1.388	<.001	4.009 (3.086, 5.208)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.269	0.069	1.309 (0.979, 1.750)	
	College and above for either parent's education level (Yes vs No) ^[1]	-0.025	0.811	0.975 (0.795, 1.197)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.418	<.001	0.242 (0.183, 0.322)	75.77% (67.84%, 81.75%)
G9	Age of onset (in months) (Continuous) ^[1]	0.030	<.001	1.031 (1.023, 1.039)	
	Residence location (Urban vs Rural) ^[1]	0.058	0.670	1.060 (0.812, 1.384)	
	Regions of study hospitals (Central vs East) ^[1]	0.205	0.245	1.228 (0.869, 1.735)	

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.5, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

Table 14.6.6. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 5) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (% , 95% CI)
	Regions of study hospitals (West vs East) ^[1]	1.248	<.001	3.483 (2.633, 4.608)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.097	0.507	1.102 (0.827, 1.469)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.552	<.001	0.576 (0.419, 0.792)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.768	<.001	0.171 (0.115, 0.253)	82.94% (74.71%, 88.49%)
P[4]	Age of onset (in months) (Continuous) ^[1]	0.025	0.026	1.025 (1.003, 1.048)	
	Regions of study hospitals (Central vs East) ^[1]	-0.047	0.916	0.954 (0.400, 2.275)	
	Regions of study hospitals (West vs East) ^[1]	0.771	0.033	2.162 (1.066, 4.383)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	1.898	0.063	6.674 (0.904, 49.282)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.482	0.374	1.620 (0.559, 4.694)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	1.503	0.001	4.494 (1.814, 11.133)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.493	<.001	0.083 (0.020, 0.344)	91.73% (65.57%, 98.01%)
P[8]	Age of onset (in months) (Continuous) ^[1]	0.040	<.001	1.040 (1.035, 1.046)	
	Residence location (Urban vs Rural) ^[1]	-0.132	0.098	0.876 (0.749, 1.025)	
	Regions of study hospitals (Central vs East) ^[1]	0.241	0.009	1.272 (1.061, 1.526)	
	Regions of study hospitals (West vs East) ^[1]	0.512	<.001	1.668 (1.397, 1.991)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.509	<.001	1.664 (1.290, 2.146)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.234	0.007	1.263 (1.065, 1.498)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.716	<.001	0.489 (0.400, 0.597)	
	Gender (Male vs Female) ^[1]	0.115	0.133	1.121 (0.966, 1.302)	
	College and above for either parent's education level (Yes vs No) ^[1]	-0.087	0.282	0.916 (0.782, 1.074)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.703	<.001	0.182 (0.146, 0.227)	81.79% (77.26%, 85.42%)
G1P[8]	Residence location (Urban vs Rural) ^[1]	-1.138	0.026	0.320 (0.118, 0.870)	
	Gender (Male vs Female) ^[1]	1.110	0.082	3.034 (0.869, 10.593)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.177	0.035	0.113 (0.015, 0.858)	88.66% (14.18%, 98.50%)
G2P[4]	Regions of study hospitals (Central vs East) ^[1]	0.889	0.102	2.432 (0.839, 7.049)	
	Regions of study hospitals (West vs East) ^[1]	1.553	0.001	4.724 (1.821, 12.255)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.122	0.822	1.130 (0.389, 3.278)	

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.5, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available.

Table 14.6.6. Adjusted vaccine effectiveness against RVGE cases by G-type, P-type and G/P type combinations (Sensitivity analysis 5) (Continued)

Types	Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%; 95% CI)
G3P[8]	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.854	0.080	2.349 (0.904, 6.104)	94.42% (58.85%, 99.24%)
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.886	0.005	0.056 (0.008, 0.411)	
	Age of onset (in months) (Continuous) ^[1]	0.037	<.001	1.038 (1.029, 1.046)	91.54% (84.20%, 95.47%)
	Residence location (Urban vs Rural) ^[1]	-0.093	0.571	0.911 (0.660, 1.257)	
	Regions of study hospitals (Central vs East) ^[1]	-0.207	0.289	0.813 (0.554, 1.192)	
	Regions of study hospitals (West vs East) ^[1]	-0.334	0.116	0.716 (0.472, 1.086)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.985	0.002	2.679 (1.427, 5.029)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	-4.089	<.001	0.017 (0.005, 0.053)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-2.882	<.001	0.056 (0.029, 0.107)	
	College and above for either parent's education level (Yes vs No) ^[1]	-0.239	0.161	0.788 (0.564, 1.100)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-2.470	<.001	0.085 (0.045, 0.158)	
G8P[8]	Age of onset (in months) (Continuous) ^[1]	0.043	<.001	1.044 (1.037, 1.052)	76.10% (68.21%, 82.03%)
	Residence location (Urban vs Rural) ^[1]	-0.241	0.020	0.786 (0.641, 0.963)	
	Regions of study hospitals (Central vs East) ^[1]	0.360	0.002	1.434 (1.144, 1.797)	
	Regions of study hospitals (West vs East) ^[1]	0.182	0.139	1.199 (0.943, 1.526)	
	Clinical setting (Inpatient vs Outpatient) ^[1]	0.683	<.001	1.980 (1.386, 2.828)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	1.390	<.001	4.015 (3.088, 5.220)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	0.277	0.062	1.320 (0.986, 1.765)	
	College and above for either parent's education level (Yes vs No) ^[1]	-0.019	0.857	0.981 (0.799, 1.205)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.431	<.001	0.239 (0.180, 0.318)	
G9P[8]	Age of onset (in months) (Continuous) ^[1]	0.030	<.001	1.030 (1.021, 1.039)	82.77% (74.28%, 88.46%)
	Residence location (Urban vs Rural) ^[1]	0.057	0.684	1.058 (0.806, 1.389)	
	Regions of study hospitals (Central vs East) ^[1]	0.303	0.092	1.354 (0.952, 1.926)	
	Regions of study hospitals (West vs East) ^[1]	1.343	<.001	3.832 (2.871, 5.115)	
	Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) ^[1]	0.087	0.552	1.091 (0.818, 1.455)	
	Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) ^[1]	-0.720	<.001	0.487 (0.348, 0.679)	
	Gender (Male vs Female) ^[1]	0.199	0.129	1.220 (0.943, 1.578)	
	Received ROTATEQ vaccination (fixed variable, Yes vs No) ^[2]	-1.759	<.001	0.172 (0.115, 0.257)	

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.

^[1] Refer to the results of Table 14.6.5, potential confounders which are significantly different (P<0.1) between case and controls group will be included in model.

^[2] "Received ROTATEQ vaccination" is the fixed variable in the logistic regression.

VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination".

Sensitivity analysis 5: A 5th sensitivity analysis will incorporate parents' education level into the multivariate model if there is a significant difference between cases and controls.

The 5th sensitivity analysis will be performed based on the children whose parents' educational level data is available