Title	Effectiveness of ROTATEQ® when administered with intervals greater than 10 weeks between doses in children in China: an observational study of V260-077 study (V260-080)
Version identifier of the study report	Version 1.0
Date of last version of the study report	NA
EU PAS Register number	EUPAS1000000730
Active substance	G1: 2.2 × 10^6 **infectious units**; G2: 2.8 × 10^6 **infectious units**; G3: 2.2 × 10^6 **infectious units**; G4: 2.0 × 10^6 **infectious units**; P1A [8]: 2.3 × 10^6 **infectious units**
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 vaccine effectiveness of ROTATEQ® against all RVGE regardless of type when the vaccine is administered in children with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3. • Exploratory objective: To assess the vaccine effectiveness of ROTATEQ® against RVGE due to at least one of RV types G1/G2/G3/G4/G9 in children when the vaccine is administered with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.
Country of study	China
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Merck Sharp & Dohme Corp Final Repository (REDS) Date	18-JUN-2026

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
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1 ABSTRACT

Title

Effectiveness of ROTATEQ® when administered with intervals greater than 10 weeks between doses in children in China: an observational study of V260-077 study (V260-080)

Keywords

Rotavirus vaccine, rotavirus gastroenteritis, dose interval, 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. The approved immunization schedule (3 doses) in China is the same as the U.S. label: the first dose at 6–12 weeks of age, followed by subsequent doses at 4–10-week interval, with the final dose administered no later than 32 weeks of age. In contrast, the European label does not specify an upper limit for the interval between doses, provided the final dose is given before 32 weeks of age. Notably, despite the immunization schedule in the U.S. and China, both the U.S. Advisory Committee on Immunization Practices (ACIP) and Chinese expert consensus support the administration of ROTATEQ® with dosing intervals of at least 4 weeks without an upper limit.

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, a non-interventional study, V260-077 (EU PAS No. EUPAS36666), was conducted over 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 Chinese children in real-world settings. As observed retrospectively, approximately 7% of enrolled participants, who were all vaccinated in real-world settings, had received at least one dose with an interval exceeding 10 weeks after the previous dose.

This study (V260-080) aimed to analyze the VE of ROTATEQ® among V260-077 participants who had received the vaccine with at least one dose interval exceeding 10 weeks and completed all doses before 32 weeks of age.

Research Objectives and Questions

Primary objective: To assess the vaccine effectiveness of ROTATEQ® against all RVGE regardless of type when the vaccine is administered in children with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

Exploratory objective: To assess the vaccine effectiveness of ROTATEQ® against RVGE due to at least one of RV types G1/G2/G3/G4/G9 in children when the vaccine is administered with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

Study Design

Test-negative case-control design.

Setting

The study population was drawn from V260-077 and included children who had at least one dose interval greater than 10 weeks, unvaccinated controls and met the following inclusion/exclusion criteria.

The V260-077 population comprised children age-eligible to be fully vaccinated with 3 doses of ROTATEQ® and receiving treatment for acute gastroenteritis (AGE) in hospitals in real-world settings.

Subjects and Study Size

Subjects

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

- Children without collection of vaccination records
- Children who had received RV vaccines other than ROTATEQ®
- Children vaccinated with mixed RV vaccines
- Children with incomplete ROTATEQ® schedules
- Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at 6 to 12 weeks of age and the third dose no later than 32 weeks of age)
- Children with at least one dosing interval <4 weeks between doses 1 and 2 and/or 2 and 3
- Children with both vaccine dose intervals between 4-10 weeks for ROTATEQ®
- Children who had received ROTATEQ® within 14 days before the onset of AGE

Study size

This was a secondary data analysis of data from the V260-077 study population (N=7510). The analysis population for the primary objective included all children with RVGE regardless of type who had been vaccinated with at least one dosing interval >10 weeks or who had not received any rotavirus vaccine, as well as RV-negative AGE cases who had been vaccinated with at least one dosing interval >10 weeks or who had not received any rotavirus vaccine.

Variables and Data Sources

Exposure

The exposure of interest was ROTATEQ® vaccination in children with at least one dose interval exceeding 10 weeks between doses 1 and 2 and/or between doses 2 and 3.

Children were classified as "vaccinated with longer interval" if they received ROTATEQ® with at least one dose interval exceeding 10 weeks between doses 1 and 2 and/or between doses 2 and 3, and the final dose was administered at least 14 days before the onset of AGE. Children were classified as "not vaccinated" if they had not received any dose of ROTATEQ® or any other RV vaccines.

Outcome

For the primary objective, all RVGE cases regardless of type (Enzyme-Linked Immunosorbent Assay [ELISA]-positive) were classified as "cases."

For the exploratory objective, RVGE attributed to G1/G2/G3/G4/G9 were classified as "cases."

For all objectives, all RV-negative AGE cases (ELISA-negative) were classified as "controls."

Covariates

Covariates included gender, age, residence location, symptom onset season, birth season, region of study hospital, clinical setting, and parents' education level. In sensitivity analysis 3 (propensity score matching followed by conditional logistic regression) and sensitivity analysis 5 (including parents' education level in the multivariate model), parents' education level was included as an additional covariate.

Data Sources

This study analyzed anonymized data previously collected for the V260-077 study and stored in an Electronic Data Capture (EDC) system. No additional informed consent was required, as only anonymized data was used, and no new patient information was collected. The study (V260-080) was approved by the Ethics Committee of Beijing Children's Hospital (approval No. [2025]-Y-198-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: Rotavirus Group A was detected by ELISA, and ELISA-positive samples were genotyped for VP7 and VP4 using multiplex reverse-transcription PCR (RT-PCR). Children who had received the vaccine with at least one dosing interval > 10 weeks were excluded from the V260-077 analysis population.

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 exploratory objective, crude and adjusted odds ratios (OR) for the exposure of interest (ROTATEQ® vaccination with at least one dosing interval > 10 weeks) for cases compared with controls were estimated using univariate and multivariate logistic regression. VE was calculated as (1 – OR) ×100%, along with 95% confidence intervals (CIs) for both crude and adjusted estimates.

Covariates were compared between cases and 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 with at least one dosing interval > 10 weeks) and AGE status (all RVGE regardless of type or RVGE attributed to G1/G2/G3/G4/G9, versus RV-negative AGE). These estimates were provided only if the regression models achieved convergence using the SAS 9.4 default settings.

Sensitivity analyses were performed for the primary and exploratory endpoints, 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:

- Sensitivity analysis 1: Included participants without confirmed vaccination information in the primary endpoint analysis, assuming that all children with missing vaccination data were unvaccinated.

- 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 ≥0.1.

- Sensitivity analysis 3: Propensity score matching (PSM) followed with appropriate controls 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 onset date. For both primary and exploratory 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.

- Sensitivity analysis 4: PSM followed by conditional logistic regression with matching factors: age of onset (in months), gender, and symptom onset seasons. For both primary and exploratory 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.

- Sensitivity analysis 5: Included parents' education level in 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 all RVGE regardless of types)

Analysis Population

A total of 7510 children with AGE were enrolled in study V260-077. Of these, 4192 were included in the analysis population. The most frequent reasons for exclusion from the analysis population were receipt of ROTATEQ® with both dose intervals ≤10 weeks (n = 1668, 22.2%), followed by receipt of RV vaccines other than ROTATEQ® (n = 1092, 14.5%) and incomplete ROTATEQ® vaccination schedules (n = 405, 5.4%). Other reasons included missing vaccination records (n = 138, 1.8%), mixed RV vaccines use (n = 7, 0.1%), vaccination outside the age-indication (age indication: the first dose to be administered at 6 to 12 weeks of age and the third dose at no later than 32 weeks of age) (n = 64, 0.9%), receipt of ROTATEQ® within 14 days before AGE onset (n = 56, 0.7%), and dose intervals of <4 weeks (n = 27, 0.4%). After exclusion, 4192 RVGE cases, comprising 1518 RVGE cases (16 with at least one dose interval >10 weeks and 1502 unvaccinated) and 2674 RV-negative AGE controls (164 with at least one dose interval >10 weeks and 2510 unvaccinated) were included in the analysis population.

Demographic Characteristics

A statistically significant difference was observed for age of onset between the RVGE cases (all RVGE regardless of types) and controls (P <0.001) in the univariate analysis. The median age at onset was 19.2 months (Interquartile Range [IQR]: 13.7–28.2) in RVGE cases and 14.4 months (IQR: 9.3–22.4) in controls. Children's AGE onset most commonly occurred at age 12-23 months (49.8% among cases and 40.4% among controls), followed by ≤11 months (17.5% among cases and 37.7% among controls).

In both RVGE cases and controls, most AGE participants were from urban areas (>60%, comparing to rural areas) and among inpatients (>86%, comparing to outpatients).

Approximately 58% of both RVGE cases and controls were born during RV peak seasons. Among cases, symptom 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 accounted for 27.3%, 29.4%, 13.2%, and 30.1% of the overall cases, respectively. In controls, the corresponding proportions were 7.5%, 33.5%, 28.8%, and 30.2% for each peak season, respectively.

Significant differences between RVGE cases and controls were observed for the 1st and 3rd seasons (both P <0.001).

No significant gender difference was observed between RVGE cases and controls, with males accounting for 62.1% of RVGE cases and 60.7% of controls. Regarding parental education, 44.8% of parents from cases had a college-level education or higher, versus 60.1% from controls. In both groups among 16 RVGE cases and 164 controls who were vaccinated with at least one interval of >10 weeks, most children received ROTATEQ® with one dose interval >10 weeks and the other ≤10 weeks (93.8% [15/16] in cases; 99.4% [163/164] in controls). Details of the descriptive data are presented in Table 1.

Primary endpoint analysis and its sensitivity analyses

In the primary endpoint analysis, 16 children (1.1%, 16/1518) in the RVGE case group and 164 (6.1%, 164/2674) in the control group were fully vaccinated with 3 doses of ROTATEQ® with at least one dose interval >10 weeks.

The crude VE of ROTATEQ® against RVGE regardless of type was 83.7% (95% CI: 72.7%–90.3%). When adjusted for potential confounders (age at onset, residence location, region of study hospital, clinical setting and symptom onset season) using an unconditional multivariate logistic regression model, the VE was 83.1% (95% CI: 71.0%–90.1%). The crude and adjusted VE estimates of the primary endpoint are presented in Table 3 and Table 4, respectively.

Sensitivity analyses of the primary endpoint, ranged from 82.6% to 87.7% and demonstrated statistically significant and consistent results under different assumptions. A summary of the sensitivity analyses is presented in Table 7.

Exploratory Objective (VE against RVGE due to G1/G2/G3/G4/G9)

Demographic Characteristics

A statistically significant difference was observed for age at onset between cases (G1/G2/G3/G4/G9 RVGE) and controls in the univariate analysis (P <0.001) with cases being approximately 5 months older at AGE onset than controls (mean: 22.9 vs. 18.0 months).

Among RVGE cases due to G1/G2/G3/G4/G9, 39.4%, 13.5%, 10.6%, and 36.5% of cases (G1/G2/G3/G4/G9 RVGE) were enrolled 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, respectively. Among controls, 7.5%, 33.5%, 28.8%, and 30.2% were enrolled in each of the 4 peaks seasons, respectively. Significant differences in odds of being a case were observed for the 1st through 3rd peak seasons, compared to the 4th season (P <0.001 for all 3 peak seasons).

Exploratory endpoint analysis and its sensitivity analyses

In the exploratory endpoint analysis, 11 children (1.2%, 11/942) in RVGE cases (due to G1/G2/G3/G4/G9) and 164 (6.1%, 164/2674) in the controls were fully vaccinated with 3 doses of ROTATEQ® with at least one dose interval >10 weeks. The crude VE of ROTATEQ® against RVGE attributable to RV types G1/G2/G3/G4/G9 was 81.9% (95% CI: 66.6%–90.2%). After adjustment for potential confounders (age of onset, residence location, region of

study hospital, and symptom onset season) using an unconditional multivariate logistic regression model, the VE was 81.7% (95% CI: 64.9%–90.5%). Crude and adjusted VE estimates for the exploratory endpoint are presented in Table 5 and Table 6, respectively.

For the exploratory endpoint, VE of ROTATEQ® against RVGE due to G1/G2/G3/G4/G9 when administered with >10 weeks of dosing intervals ranged from 80.5% to 86.1% and demonstrated statistically significant and consistent results under different assumptions in the sensitivity analyses. A summary of the sensitivity analyses is presented in Table 7.

Discussion

The observed high effectiveness of ROTATEQ® in children who had received the vaccine doses with intervals exceeding 10 weeks in this study is consistent with the vaccine efficacy results from post hoc analyses of the global REST trial, which supported current recommendations in the EMA label and ACIP guidelines, as well as the China expert consensus. In the REST trial, the primary efficacy analysis included infants vaccinated with dose intervals of at least 4 weeks. A post hoc analysis of infants who received a dose more than 10 weeks after the previous dose showed a 100% reduction (95% CI: 60%–100%) in hospitalization and/or emergency visits for RVGE, regardless of serotype.

Sensitivity analyses using alternative assumptions yielded consistent results across both endpoints, indicating that VE results for ROTATEQ® with longer dose intervals (>10 weeks) were reliable and robust. Moreover, real-world studies offer an opportunity to assess VE under real-world conditions, which may supplement clinical trials. The findings from this study provide real-world evidence supporting greater flexibility in vaccination strategies for public health, particularly by allowing longer dosing intervals between doses.

Strength of the data source and the study design

This study used data source that previously collected for an MSD-sponsored large, multicenter post-marketing study (V260-077) that was conducted during four RV peak seasons at 37 study sites in 15 provinces across eastern, central, and western China, enrolling 7510 patients. 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 biases due different healthcare-seeking behaviors among cases and controls.

Furthermore, the study addressed a key evidence gap regarding ROTATEQ® administration with longer dosing intervals in Chinese children, as observed in routine practice, providing actionable insights to support increased flexibility in the immunization schedule.

Conclusion

ROTATEQ® administered with dose intervals >10 weeks provides strong protection against RVGE regardless of type among children in China.

Marketing Authorisation Holder(s)

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Names and affiliations of principal investigators

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Affiliation: Beijing Children's Hospital, Capital Medical University

2 LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AGE	Acute gastroenteritis
CDE	Center for Drug Evaluation
CI	Confidence interval
CSR	Clinical study report
EC	Ethics Committee
EDC	Electronic data capture
ELISA	Enzyme-linked immunosorbent assay
EMA	European Medicines Agency
EU PAS	European Union Post-Authorisation Studies Register
GPP	Good Pharmacoepidemiology Practice
ICF	Informed consent form
IQR	Interquartile range
IRB	Institutional Review Board
IV	Intravenous
max	Maximum
min	Minimum
MSD	Merck Sharp & Dohme
n	Number of participants
nmiss	Number of patients with missing variable information
OR	Odds ratio
PRS	Program requirements and specification
PSM	Propensity score matching
Q1	25th percentile
Q3	75th percentile
REST	Rotavirus Efficacy and Safety Trial
ROTATEQ®	Reassortant Rotavirus Vaccine, Live, Oral, Pentavalent (Vero Cell)
RT-PCR	Reverse-transcription polymerase chain reaction
RV	Rotavirus
RVGE	Rotavirus gastroenteritis
SAS	Statistical Analysis System
SD	Standard deviation
SQI	Significant Quality Issue
VE	Vaccine effectiveness
WC3	Wistar Calf 3 (bovine rotavirus strain)
WHO	World Health Organization

3 INVESTIGATORS

Role	Name / Affiliation
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Vendor	Hangzhou Tigermed Consulting Co., Ltd.

4 OTHER RESPONSIBLE PARTIES

Not applicable.

5 MILESTONES

Milestone	Planned date	Actual date
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
Interim report of study results	Not applicable	Not applicable
Final report of study results	Q2 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

Rotavirus (RV) is the leading cause of severe diarrhea in infants and young children in China and worldwide. In 2009, the World Health Organization (WHO) recommended RV vaccination for all children worldwide, especially in countries with a high number 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. Over 50% of RV-related hospitalizations in China occurred by age 1 year and about 90% occurred by age 2 years [Ref. 5.4: 047QHG], 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].

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 rotavirus vaccine indicated for the prevention of rotavirus gastroenteritis (RVGE) in infants and children caused by the types G1, G2, G3, G4, and G9 [Ref. 5.4: 08NSP2]. ROTATEQ® has a stringent immunization schedule approved in China, with the first dose to be administered at age 6 to 12 weeks, subsequent doses with a 4- to 10-week interval, and the third dose administered no later than 32 weeks of age [Ref. 5.4: 08NSP2].

In the Rotavirus Efficacy and Safety Trial (REST), the global pivotal Phase 3 efficacy study that supported the vaccine's approval worldwide, the efficacy of ROTATEQ® was demonstrated in the per-protocol population, which included participants vaccinated with 3 doses at intervals of at least 4 weeks and no upper limit between doses [Ref. 5.4: 08NPVR]. A post hoc evaluation was conducted among infants who had received a dose more than 10 weeks after the previous dose. The rate reduction for the combined endpoint against hospitalization and/or emergency department visits for RVGE, regardless of type, was 100% (95% confidence interval [CI]: 60%, 100%) [Ref. 5.4: 03PZF8]. The results from this post-hoc analysis showed that the combined end point of hospitalizations and/or emergency department visits for RVGE was comparatively effective.

Across European Medicines Agency (EMA) countries, the ROTATEQ® schedule is indicated with no upper interval limits between doses 1 and 2 or doses 2 and 3, provided no dose is given after 32 weeks of age [Ref. 5.4: 090FC3]; according to the Advisory Committee on Immunization Practices (ACIP) and in the US and the China expert consensus recommendations, ROTATEQ® can also be administered with dose intervals of greater than 10 weeks [Ref. 5.4: 03RHMM], [Ref. 5.4: 095FH4]. In the clinical efficacy trial conducted in China (V260-024), most participants in the vaccination group received doses at approximately 4-week intervals [Ref. 5.4: 04V9CN]. Additionally, no study has examined the efficacy or effectiveness of ROTATEQ® with longer dosing intervals among Chinese children in the real-world.

At the time of ROTATEQ®'s marketing authorization in China, the Center for Drug Evaluation (CDE) required the establishment of a follow-up database to continuously monitor its effectiveness against RVGE caused by G2, G3, and G4 types in a broader population. To fulfil this post-marketing requirement, study V260-077 (EU PAS No. EUPAS36666) was conducted across four RV peak seasons to assess the vaccine effectiveness (VE) of ROTATEQ® against RVGE caused by types G2/G3/G4 and G1/G2/G3/G4/G9 in Chinese children. As observed retrospectively in real-world settings, approximately 7% of enrolled participants, who were all vaccinated in real-world settings, had received at least one dose with an interval exceeding 10 weeks after the previous dose.

Currently, there is insufficient evidence regarding the protection of ROTATEQ® when administrated with extended dosing intervals to children in China under real-world conditions. Therefore, V260-077 study participants who had received ROTATEQ® with longer dosing intervals through routine care were included in the present study (V260-080) to evaluate the effectiveness of ROTATEQ® with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

7 RESEARCH QUESTION AND OBJECTIVES

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

Primary Objective

- To assess the vaccine effectiveness of ROTATEQ® against all RVGE regardless of type when the vaccine is administered in children with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

Exploratory Objective

- To assess the vaccine effectiveness of ROTATEQ® against RVGE due to at least one of RV types G1/G2/G3/G4/G9 in children when the vaccine is administered with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3.

8 PROTOCOL AMENDMENTS AND UPDATES

Amendment or Update No.	Approval Date	Section	Amendment or Update	Reason	Version No.
<1> Original	23 July 2025	—	—	—	V1.0

9 RESEARCH METHODS

9.1 Study Design

The study (V260-080) was conducted using only structured secondary data from the post-licensure study V260-077. No prospective data collection was conducted for this study. A test-negative case-control design was used. Children treated for AGE in hospital settings and with documented RV testing were classified as cases if the RV test was ELISA-positive (primary objective), and ELISA positive with detection of G1/G2/G3/G4/G9 by PCR (exploratory objective). All children with ELISA-negative results were considered as controls. VE was estimated by comparing the odds of ROTATEQ® vaccination with at least one dose interval greater than 10 weeks between doses to those unvaccinated among cases versus controls.

VE was estimated for (1) RVGE regardless of type and (2) RVGE against G1/G2/G3/G4/G9.

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 acute gastroenteritis (AGE) in hospitals and had documented RV test results.

In the V260-077 study, RV testing used enzyme-linked immunosorbent assay (ELISA) for RV antigen detection, and ELISA-positive specimens underwent 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.

The analysis population included children who had at least one dose interval greater than 10 weeks and met the prespecified inclusion/exclusion criteria.

"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. In the V260-077 study, 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). The present study is a secondary use of data from V260-077 study and therefore adopts the same study duration period.

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 who had received RV vaccines other than ROTATEQ®
- Children vaccinated with mixed RV vaccines
- Children with incomplete ROTATEQ® schedule
- Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at 6 to 12 weeks of age and the third dose no later than 32 weeks of age)
- Children with at least one dose interval < 4 weeks vaccination between 1 and 2 and/or 2 and 3 dose intervals
- Children with both vaccine dose intervals between 4-10 weeks for ROTATEQ®
- Children who had received 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 the primary and exploratory objectives in this report. Exposure group definitions and endpoint definitions are provided in Sections 9.4.1 and 9.4.2.

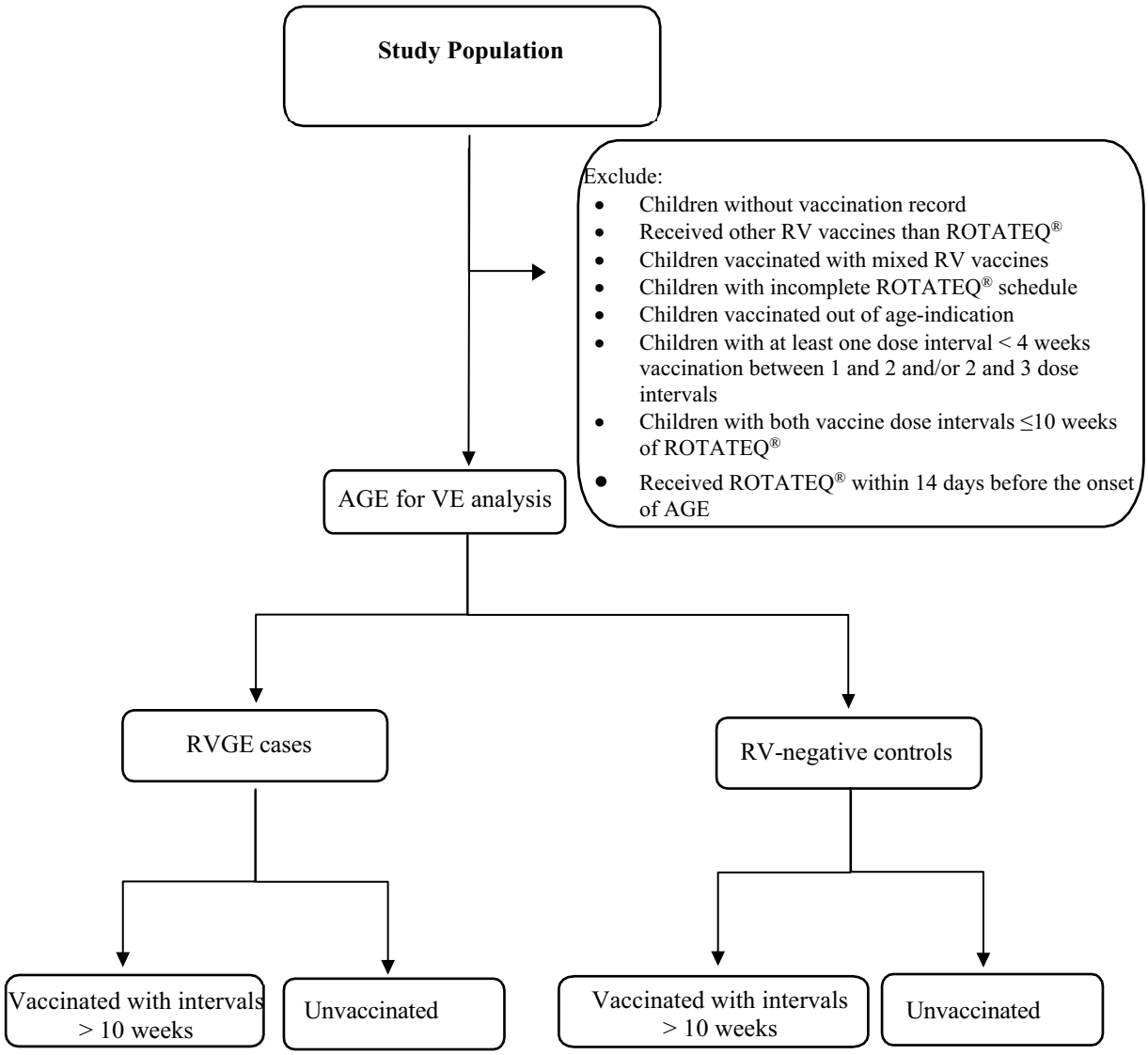

Figure 1. Flow chart to assess the effectiveness of ROTATEQ® against RVGE when administered with intervals greater than 10 weeks

Note: Days before AGE onset were calculated as the difference between the AGE onset date and the vaccination date (AGE onset date − vaccination date).

9.4 Variables

9.4.1 Exposure

The study exposure of interest was ROTATEQ® vaccination in children with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or between doses 2 and 3.

Children were classified as "vaccinated with longer interval" if they received the vaccine with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or between doses 2 and 3, and the last dose was administered at least 14 days before the onset of AGE. Children were classified as "unvaccinated" if they had not received any dose of ROTATEQ® or any other RV vaccine.

9.4.2 Outcome

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

Primary Objective:

- All RVGE cases regardless of type (ELISA-positive) were defined as “cases”.
- All RV-negative AGE cases (ELISA-negative) were defined as controls

Exploratory Objective:

- RVGE cases attributable to RV types G1/G2/G3/G4/G9 were defined as cases.
- All RV-negative AGE cases (ELISA-negative) were defined as controls

9.4.3 Covariates

- Gender
- Age at onset
- Residence location
- Symptom onset season
- Birth season
- Region of study hospital
- Clinical setting
- Parents’ education level

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. This study (V260-080) was approved by the Ethics Committee of Beijing Children's Hospital (approval No. [2025]-Y-198-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, and for ELISA-positive samples, multiplex reverse-transcription polymerase chain reaction (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

For the primary objective, the numbers of vaccinated with intervals greater than 10 weeks RVGE (regardless of type) cases, unvaccinated RVGE (regardless of type) cases, vaccinated with intervals greater than 10 weeks RV (-) AGE cases, and unvaccinated RV (-) AGE cases were summed up based on RV testing, and ROTATEQ® vaccination with intervals greater than 10 weeks histories for each eligible AGE case.

For the exploratory objective, RVGE cases attributable to G1/G2/G3/G4/G9 were considered as cases and RV (-) AGE as controls.

Odds ratios for exposure of interest in cases compared with test-negative controls were estimated. The VE will be calculated as (1-odds ratio) × 100%.

9.6 Bias

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 enrolment departments (outpatient, emergency, inpatient) were chosen to cover the core hospital departments whenever possible. Measures were applied to ensure continuous enrolment of cases to reduce selection bias. To avoid selection bias during enrolment 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 analysis of data from the V260-077 study population (N=7510). The analysis population for the primary objective included all children with RVGE regardless of type who had been vaccinated with at least one dose interval >10 weeks between doses or who had not received any rotavirus vaccine, as well as RV-negative AGE cases who had been vaccinated with at least one dose interval >10 weeks between doses or who had not received any rotavirus vaccine.

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 (AGE onset date − birth date + 1 day) / 30.4367; age at onset in weeks, calculated as (AGE onset date − birth date + 1 day) / 7; and age at the time of signing the informed consent form (ICF) in months, calculated as (ICF date − birth date + 1 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 program requirements and specification document (PRS).

- Developing and testing statistical programs, which includes ensuring the programs 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 programs and are consistent with the PRS.

- Independent review and testing, conducted by a second programmer, to ensure that the input and outputs of the programs created by the first programmer meet the documented PRS. This includes the following 2 activities: (i) review of code to ensure the program aligns with the PRS; (ii) execution of code and review of results for all scenarios. It may also include parallel programming of a small piece of critical code.

- Independent double programming, conducted by the second programmer. After programming is completed, the programs and results of the second programmer are compared with those of the first programmer to ensure consistency. If discrepancies are found, the programmers 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. For continuous variables, the number of patients having the variable information (non-missing patients, n), number of patients missing the variable information (missing patients, nmiss), mean, standard deviation (SD), 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; mean, median, Q1, and Q3 were rounded to 1 decimal place more than the original data; SD was rounded to 1 decimal place more than the original data.

Odds ratio (OR) was retained to 3 decimals, and regression coefficient and P value were retained to 3 decimals. For categorical variables, the number of patients in each category and the percentage were presented; percentage was rounded to 1 decimal place. The lower and upper bounds of confidence intervals (CIs) were rounded to 2 decimal places.

9.9.2 Main Statistical Methods

Design and analytic framework

This was a test-negative case-control analysis.

The exposure of interest was ROTATEQ® vaccination with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3, and ≥14 days before AGE onset.

Endpoints and case definitions

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

- **Exploratory objective**: Cases were RVGE attributable to RV types G1/G2/G3/G4/G9. Controls remained RV-negative AGE (ELISA-negative).

Study Population

The study population was drawn from V260-077 and included children who had at least one dose interval greater than 10 weeks.

Analysis Population

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

- Children without collection of vaccination records
- Children who had received RV vaccines other than ROTATEQ®
- Children vaccinated with mixed RV vaccines
- Children with incomplete ROTATEQ® schedules
- Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at 6 to 12 weeks of age and the third dose no later than 32 weeks of age)
- Children with at least one dose interval <4 weeks vaccination between 1 and 2 and/or 2 and 3 dose intervals
- Children with both vaccine dose intervals between 4-10 weeks for ROTATEQ®
- Children who had received ROTATEQ® within 14 days before the onset of AGE

Estimation of crude and adjusted VE

For both the primary objective and the exploratory objective, crude and adjusted odds ratios (OR) for ROTATEQ® vaccination with at least one dose intervals >10 weeks for cases compared to controls were estimated using univariate and multivariate logistic regression.

VE was calculated as (1 – OR) ×100%, along with 95% confidence intervals (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 (vaccinated with at least one dose interval >10 weeks vs. unvaccinated) 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's age at onset, gender, residence location, symptom onset season, birth season, study hospital region, and clinical setting; parents'

education level was incorporated in specified sensitivity analyses and/or when imbalance criteria were met.

Statistical programming was performed using SAS version 9.4.

Subgroup analyses

Subgroup analyses: the unadjusted VE and 95% confidence interval (CI) were analyzed in subgroups by age of onset group (≤11 months, 12-23 months, 24-35 months, ≥36 months), gender (male, female), birth seasons (RV peak season, Non-RV peak season), symptom onset seasons (2020/10-2021/3, 2021/10-2022/4, 2022/10-2023/4, 2024/10-2025/4), residence locations (Urban, Rural), clinical setting (Inpatient, Outpatient) and regions of study hospitals (East, Central, West).

9.9.3 Missing Values

For the primary and exploratory 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 exploratory endpoint (VE against RVGE attributable to G1/G2/G3/G4/G9) when the data were sufficient to support model estimation and convergence. These analyses were conducted to evaluate the reliability and robustness of VE estimates under alternative assumptions related to vaccination ascertainment and confounding control.

- **Sensitivity analysis 1**

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

Considering the rotavirus vaccine is paid out of pocket, it is probably more likely that parents from vaccinated children can 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 will be directly included in the unconditional multivariate logistic regression model, regardless of their P-values in the univariate logistic regression, even if P >= 0.1.

The sensitivity analysis 2 will be based on the V260-080 analysis population and refer to the unconditional univariate logistic regression analysis results of the primary and exploratory endpoint.

- **Sensitivity analysis 3- Propensity Score Matching and Conditional Logistic Regression**

Propensity Score Matching (PSM) will be used, and a 3rd sensitivity analysis will be 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), onset date. That is, 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, college and above for either parent's education level, onset date). 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 will be used to allow the utmost of matched pairs, if the number permits. For the exploratory endpoint, if the number of controls allows, an up to 1:3 PSM will be used.

Based on the above matched sample, univariate analysis for potential confounders (including birth seasons, residence locations, regions of study hospitals and clinical setting) will be performed. Dependent variable is group (case group, control group). And the significant factors from the conditional univariate logistic regression will be included in the conditional multivariate logistic regression model to obtain OR, 95% CI of OR, and P value 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 are same as unconditional logistic regression model.

The 95% CI of OR will be calculated using the normal approximation, and the 95% CI of VE will be calculated.

- **Sensitivity analysis 4- Propensity Score Matching and Conditional Logistic Regression**

PSM will be used and a 4th sensitivity analysis will be conducted using the matching factors: age of onset (in months), gender, onset date. That is, 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, onset date).

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) will be performed. And the significant factors from the conditional univariate logistic regression will be included in the conditional multivariate logistic regression model to obtain OR, 95% CI of OR, and P value 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 are same as unconditional logistic regression model.

The 95% CI of OR will be calculated using the normal approximation, and the 95% CI of VE will be calculated.

Sensitivity analysis 5- Unconditional Logistic Regression

A 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 will be conducted if the difference of educational level of the children's parents is significant between the case and control groups. The 5th sensitivity analysis will be performed based on the children whose data of educational level of the children's parents and potential confounders described above in section 9.4.3 are available.

Due to limited information available in peak season 1, this analysis will be included only in the sensitivity analysis and excluded from the primary analysis.

Univariate analysis for potential confounders described above in section 9.4.3 and educational level of the children's parents will be performed. And the significant factors from the univariate logistic regression will be included in the unconditional multivariate logistic regression model to obtain OR, 95% CI of OR, and P value for comparing the ratio of ROTATEQ® vaccination among cases with at least one dosing interval greater than 10 weeks between dose 1 and 2 and/or between 2 and 3 and controls after adjusting the potential confounders for with $P < 0.1$.

The 95% CI of OR will be calculated using the normal approximation, and the 95% CI of VE will be calculated.

9.9.5 Amendments to the Statistical Analysis Plan

Any deviations from or amendments to the prespecified analysis approach (if applicable) were documented within the clinical study report (CSR) / Statistical Analysis Plan documentation.

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 Pharmacoepidemiology 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; 4192 met eligibility criteria for the analysis population of V260-080 study, comprising 1518 RVGE cases (16 with at least one dose interval >10 weeks and 1502 unvaccinated) and 2674 RV-negative AGE controls (164 with at least one dose interval >10 weeks and 2510 unvaccinated). The crude and adjusted VE of ROTATEQ® with at least one dose interval >10 weeks against RVGE regardless of type were 83.7% (95% CI: 72.7%–90.3%) and 83.1% (95% CI: 71.0%–90.1%), respectively. VE against RVGE regardless of type ranged from 82.6% to 87.7% under different assumptions in the sensitivity analyses. The crude and adjusted VE against RVGE attributable to RV types G1/G2/G3/G4/G9 were 81.9% (95% CI: 66.6%–90.2%) and 81.7% (95% CI: 64.9%–90.5%), respectively. VE against RVGE due to G1/G2/G3/G4/G9 ranged from 80.5% to 86.1% under different assumptions in the sensitivity analyses. 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.

In V260-077 study, investigators should ensure that personal identifiers were removed from any study files that were 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

The population is defined as the V260-077 study population (N = 7510), including children who had at least one dose interval greater than 10 weeks.

10.1.3 Analysis Population

From the study population of 7510 children, a total of 4192 children (55.8%) met the prespecified eligibility criteria for inclusion in the V260-080 analysis population.

A total of 7510 children with AGE were enrolled in the study. Of these, 4192 were included in the analysis population, comprising 1518 RVGE cases (16 with at least one dose interval >10 weeks and 1502 unvaccinated) and 2674 RV-negative AGE controls (164 with at least one dose interval >10 weeks and 2510 unvaccinated). The most frequent reasons for exclusion from the analysis population were receipt of ROTATEQ® with both dose intervals ≤10 weeks (n = 1668, 22.2%), followed by receipt of RV vaccines other than ROTATEQ® (n = 1092, 14.5%) and incomplete ROTATEQ® vaccination schedules (n = 405, 5.4%). Other reasons included missing vaccination records (n = 138, 1.8%), mixed RV vaccines use (n = 7, 0.1%), vaccination outside the age-indication (age indication: the first dose to be administered at 6 to 12 weeks of age and the third dose at no later than 32 weeks of age) (n = 64, 0.9%), receipt of ROTATEQ® within 14 days before AGE onset (n = 56, 0.7%), and dose intervals of <4 weeks (n = 27, 0.4%) (see Table 14.1.1).

A child may have met multiple exclusion criteria; therefore, the sum of individual category counts may exceed the total number of excluded children. 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%) had unknown status for partial vaccination information. Due to the inability to ascertain RV vaccination status, a sensitivity analysis to estimate the VE was performed by assuming those participants without confirmed vaccination information being unvaccinated. (see Table 14.2.4).

10.1.5 Final Analysis Population Composition

The final analysis population (N=4192) comprised 1518 RVGE cases and 2674 RV-negative AGE controls. Among the RVGE cases, 16 children had received 3 doses of ROTATEQ® with at least one dosing interval >10 weeks and 1502 children were unvaccinated. Among the RV-negative AGE controls, 164 children had received 3 doses of ROTATEQ® with at least one dosing interval >10 weeks and 2510 children were unvaccinated Among the 180 vaccinated children included in the final analysis population, 178 (98.9%) had one dosing interval >10 weeks and one dosing interval ≤10 weeks, and 2 (1.1%) had both dosing intervals >10 weeks (see Table 14.2.4). The flow of participants from enrolment through analysis population derivation is depicted in Figure 2.

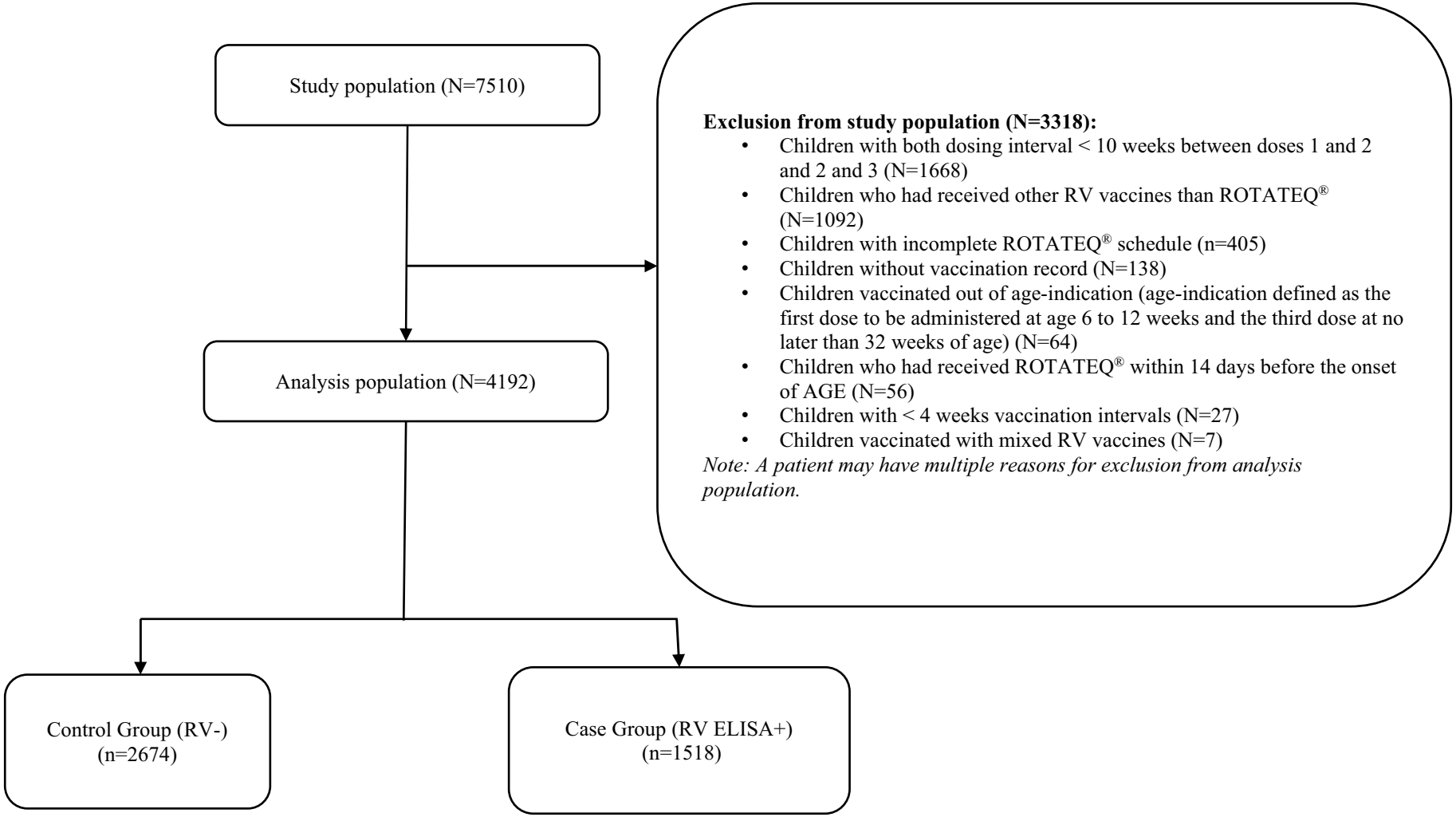

Figure 2. Flow chart of analysis dataset for primary objective

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 4192 children, including 1518 RVGE cases (ELISA-positive) and 2674 RV-negative controls (ELISA-negative). A statistically significant difference was observed for age of onset between the case and control groups ($P < 0.001$) in the univariate analysis. The median age at onset was 19.2 months (Interquartile Range [IQR]: 13.7–28.2) in the RVGE case group and 14.4 months (IQR: 9.3–22.4) in the control group. The mean age at onset was 23.25 months (SD: 14.50) for cases and 17.98 months (SD: 12.54) for controls. AGE onset occurred most frequently at 12–23 months (49.8% of cases; 40.4% of controls), followed by ≤11 months (17.5% of cases; 37.7% of controls).

No significant gender difference was observed between RVGE cases and controls, with males accounting for 62.1% of cases and 60.7% of controls. Urban residence was common in both groups (60.4% of RVGE cases; 63.3% of controls), and most children were managed as inpatients (89.2% of RVGE cases; 86.8% of controls). Distributions by region of study hospitals and symptom onset season differed between RVGE cases and controls: the proportion of cases from Western regions (34.1%) was significantly higher than the corresponding proportion among controls (26.0%; $P < 0.001$), and the proportions of RVGE cases arising during the 1st (Oct 2020–Mar 2021) and 3rd (Oct 2022–Apr 2023) peak seasons differed significantly from the 4th (reference) season (both $P < 0.001$). Parents' education data were incomplete, with greater missingness among cases (28.1%) than among controls (8.2%).

Demographic and clinical characteristics of the RVGE case and control groups are summarized in Table 1.

A statistically significant difference was observed for age at onset between cases (G1/G2/G3/G4/G9 RVGE) and controls in the univariate analysis ($P <0.001$). Univariate analysis showed that cases were approximately 5 months older at AGE onset than controls (mean: 22.9 vs. 18.0 months). Significant differences were also observed between cases (G1/G2/G3/G4/G9 RVGE) and controls among regions of study hospitals ($P <0.001$).

Among RVGE cases due to G1/G2/G3/G4/G9, 39.4%, 13.5%, 10.6%, and 36.5% of cases (G1/G2/G3/G4/G9 RVGE) were enrolled 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, respectively. In controls, the corresponding proportions were 7.5%, 33.5%, 28.8%, and 30.2%, respectively. Significant differences between RVGE cases (due to G1/G2/G3/G4/G9) and controls were observed for the 1st through 3rd peak seasons ($P <0.001$ for all 3 peak seasons). Detailed descriptive data are presented in Table 1.

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

		Cases (all RVGE regardless of types)	Cases (due to G1/G2/G3/G4/G9 RVGE)	Controls (RV -)	Total
Age of onset (in months)	n (nmiss)	1518 (0)	942 (0)	2674 (0)	4192 (0)
	Mean (Std)	23.25 (14.497) ***	22.92 (14.523) ***	17.98 (12.537)	19.89 (13.518)
	Median	19.20	18.85	14.40	16.00
	Q1, Q3	13.70, 28.20	13.50, 26.60	9.30, 22.40	10.70, 24.30
	Min, Max	3.8, 78.0	4.1, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	265 (17.5)	170 (18.0)	1007 (37.7)	1272 (30.3)
	12-23 months	756 (49.8)	484 (51.4)	1079 (40.4)	1835 (43.8)
	24-35 months	251 (16.5)	141 (15.0)	331 (12.4)	582 (13.9)
	>=36 months	246 (16.2)	147 (15.6)	257 (9.6)	503 (12.0)
Birth seasons (n, %) [1]	RV peak season	884 (58.2)	548 (58.2)	1529 (57.2)	2413 (57.6)
	Non-RV peak season#	634 (41.8)	394 (41.8)	1145 (42.8)	1779 (42.4)
Residence location (n, %)	Urban	917 (60.4)	566 (60.1)	1693 (63.3)	2610 (62.3)
	Rural#	599 (39.5)	374 (39.7)	981 (36.7)	1580 (37.7)
	Missing	2 (0.1)	2 (0.2)	0	2 (0.05)
Regions of study hospitals (n, %) [2]	East#	622 (41.0)	358 (38.0)	1299 (48.6)	1921 (45.8)
	Central	378 (24.9)	203 (21.5)	680 (25.4)	1058 (25.2)
	West	518 (34.1) ***	381 (40.4) ***	695 (26.0)	1213 (28.9)
Clinical settings (n, %)	Inpatient	1354 (89.2) *	828 (87.9)	2322 (86.8)	3676 (87.7)
	Outpatient#	164 (10.8)	114 (12.1)	352 (13.2)	516 (12.3)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	415 (27.3) ***	371 (39.4) ***	200 (7.5)	615 (14.7)
	2021/10-2022/4	446 (29.4)	127 (13.5) ***	895 (33.5)	1341 (32.0)
	2022/10-2023/4	200 (13.2) ***	100 (10.6) ***	771 (28.8)	971 (23.2)
	2024/10-2025/4#	457 (30.1)	344 (36.5)	808 (30.2)	1265 (30.2)
Gender (n, %)	Male	942 (62.1)	586 (62.2)	1623 (60.7)	2565 (61.2)
	Female#	576 (37.9)	356 (37.8)	1051 (39.3)	1627 (38.8)
College and above for either parent's education level (n, %)	No	411 (27.1)	196 (20.8)	847 (31.7)	1258 (30.0)
	Yes	680 (44.8)	371 (39.4)	1608 (60.1)	2288 (54.6)
	Missing	427 (28.1)	375 (39.8)	219 (8.2)	646 (15.4)
Vaccination Status	One dose interval > 10 weeks and one dose interval <= 10 weeks	15 (1.0)	10 (1.1)	163 (6.1)	178 (4.2)
	Both dose intervals > 10 weeks	1 (0.1)	1 (0.1)	1 (0.0)	2 (0.1)
	Unvaccinated	1502 (98.9)	931 (98.8)	2510 (93.9)	4012 (95.7)
	Total	1518 (100.0)	942 (100.0)	2674 (100.0)	4192 (100.0)

[1] RV Peak season: 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 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. *** $P < 0.001$. ** $P < 0.01$. * $P < 0.05$
Abbreviations: n: the number of participants; nmiss: the number with missing data; SD: standard deviation; Q1: 25th percentile; Q3: 75th percentile; min: minimum; max: maximum

10.2.2 Characteristics of AGE Cases at Enrollment

Among the analysis population, the mean age at AGE onset was 19.89 months (SD: 13.52). All children (100%) had diarrhea prior to hospital presentation, with a mean duration of 3.26 days (SD: 2.26; median 3.0; Q1, Q3: 2.0, 4.0). The mean maximum number of stools per day before hospital visit was 6.19 (SD: 3.21; median 5.0). The most frequent diarrhea characteristic was watery (65.2% of analysis population), followed by bloody (3.2%) and rice-washed stools (0.2%); other stool characteristics account for 42.9%. Vomiting prior to hospital presentation was reported in 2399 children (57.2% of analysis population), with a mean duration of 2.50 days (SD: 1.67) and mean maximum vomiting episodes per day of 5.02 (SD: 3.54). The most frequent vomit characteristic was gastric contents (95.5% of those with vomiting). Axillary temperature was measured in 3329 children (79.4% of analysis population), with a mean highest temperature of 38.35°C (SD: 1.25; median 38.50°C). Additional detail on pre-hospital symptom and rehydration characteristics is provided in Table 14.2.2.

10.2.3 Treatment of Acute Gastroenteritis

Among children in the analysis population, 3676 (87.7%) were admitted to inpatient wards for treatment of their AGE episode. A total of 4015 children (95.8%) received intravenous fluids with a median of 3.0 (range, 1 to 18) days, and 1269 (30.3%) received oral rehydration with a median of 3.0 (range, 1 to 13) days. Among those receiving IV rehydration, the mean duration prescribed was 3.5 days (SD: 1.88; median 3.0; range 1–18 days). Among those receiving oral rehydration, the mean duration prescribed was 3.1 days (SD: 1.91; median 3.0; range 1–13 days). Treatment patterns are summarized 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=4, 192), 1518 children (36.2%) tested positive for RV antigen and were classified as RVGE cases, whereas 2,674 children (63.8%) tested negative and were classified as RV-negative controls. The RV positivity rate among AGE presentations in the analysis population was 36.2% (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.

Table 2. Frequency of Rotavirus A G-P type combinations of analysis population (Primary Objective Analysis).

	Types	G1 (%)	G2 (%)	G3 (%)	G4 (%)	G6 (%)	G8 (%)	G9 (%)	G11 (%)	G12 (%)	G non-typable (%)	Total
Type distribution (Vaccinated with >10 wks interval)	**P[4]**	0	1 (6.3)	0	0	0	0	0	0	0	0	1 (6.3)
	P[6]	0	0	0	0	0	0	0	0	0	0	0
	P[8]	1 (6.3)	0	2 (12.5)	0	0	4 (25.0)	7 (43.8)	0	0	0	14 (87.5)
	P[9]	0	0	0	0	0	0	0	0	0	0	0
	P non-typable	0	0	0	0	0	0	0	0	0	1 (6.3)	1 (6.3)
	Total	1 (6.3)	1 (6.3)	2 (12.5)	0	0	4 (25.0)	7 (43.8)	0	0	1 (6.3)	16 (100.0)
Type distribution (not vaccinated)	**P[4]**	0	47 (3.1)	0	0	0	0	8 (0.5)	0	0	4 (0.3)	59 (3.9)
	P[6]	0	0	0	3 (0.2)	0	0	0	0	0	0	3 (0.2)
	P[8]	16 (1.1)	2 (0.1)	225 (15.0)	0	0	524 (34.9)	619 (41.2)	1 (0.1)	1 (0.1)	19 (1.3)	1407 (93.7)
	P[9]	0	0	5 (0.3)	0	0	0	0	0	0	0	5 (0.3)
	P non-typable	0	1 (0.1)	1 (0.1)	0	2 (0.1)	2 (0.1)	4 (0.3)	0	0	18 (1.2)	28 (1.9)
	Total	16 (1.1)	50 (3.3)	231 (15.4)	3 (0.2)	2 (0.1)	526 (35.0)	631 (42.0)	1 (0.1)	1 (0.1)	41 (2.7)	1502 (100.0)

The denominator was the number of patients from the V260-080 analysis population with ELISA positive results.

10.3.2.1 G-Type Distribution Among RVGE Cases

Among 1,518 RVGE cases, the predominant G types were G9 (n=638; 42.0%), G8 (n=530; 34.9%), and G3 (n=233; 15.3%). Less common G types included G2 (n=51; 3.4%), G1 (n=17; 1.1%), G4 (n=3; 0.2%), G6 (n=2; 0.1%), G11 (n=1; 0.1%), and G12 (n=1; 0.1%). A total of 42 specimens (2.8%) were G non-typable. The 3 most prevalent G types (G9, G8, and G3) together accounted for 92.2% of all RVGE cases (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 1421 cases (93.6% of typed specimens). Other P types included P[4] (n=60; 4.0%), P[9] (n=5; 0.3%), and P[6] (n=3; 0.2%). A total of 29 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=626; 41.2%), G8P[8] (n=528; 34.8%), and G3P[8] (n=227; 15.0%). Additional combinations observed included G2P[4] (n=48; 3.2%) and G1P[8] (n=17; 1.1%) (Table 14.2.6).

10.3.3 RV Type Distribution by Symptom Onset Season

The distribution of RV types and G/P combinations varied substantially across the four symptom onset seasons captured in the surveillance period.

During 2020/10–2021/03 (n=615 analysis-population RVGE cases/controls; 415 ELISA-positive, 67.5% positivity), G9 was strongly dominant (349/415; 84.1%), followed by G non-typable (27; 6.5%), G2 (21; 5.1%), and G8 (17; 4.1%). P[8] accounted for 374 (90.1%) of typed specimens, with P[4] at 22 (5.3%) (see Table 14.2.5 and 14.2.7).

During 2021/10–2022/04 (n=1341; 446 ELISA-positive, 33.3% positivity), G8 became dominant (310/446; 69.5%), followed by G9 (107; 24.0%). P[8] remained dominant at 430 (96.4%) of typed specimens (see Table 14.2.5 and 14.2.8).

During 2022/10–2023/04 (n=971; 200 ELISA-positive, 20.6% positivity), G8 remained most common (98/200; 49.0%), followed by G9 (68; 34.0%), G2 (14; 7.0%), and G3 (11; 5.5%). P[8] accounted for 173 (86.5%) of typed specimens, with P[4] at 23 (11.5%) (see Table 14.2.5 and 14.2.9).

During 2024/10–2025/04 (n=1265; 457 ELISA-positive, 36.1% positivity), G3 emerged as the most common type (216/457; 47.3%), followed by G9 (114; 24.9%) and G8 (105; 23.0%). P[8] remained predominant at 444 (97.2%) of typed specimens (see Table 14.2.5 and 14.2.10).

Across all seasons, P[8] remained the dominant P type, ranging from 86.5% to 97.2% of typed specimens.

10.4 Vaccine Effectiveness Results

10.4.1 Primary Endpoint: Vaccine Effectiveness Against RVGE Regardless of Type

10.4.1.1 Crude Vaccine Effectiveness

In the primary endpoint analysis, 16 children (1.1%, 16/1518) in the RVGE case group and 164 (6.1%, 164/2674) in the control group were fully vaccinated with 3 doses of ROTATEQ® with at least one dose interval >10 weeks. The crude VE of ROTATEQ® against RVGE regardless of type when administered with at least one dose interval >10 weeks was 83.70% (95% CI: 72.65%, 90.28%). Crude VE is presented in Table 3 (see also Table 14.3.1).

Table 3. Crude vaccine effectiveness against RVGE regardless of type when administered with vaccine dose intervals >10 weeks (Primary Objective Analysis).

	Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Vaccinated	16 (1.1)	164 (6.1)	180 (4.3)	83.70% (72.65%, 90.28%)
Unvaccinated	1502 (98.9)	2510 (93.9)	4012 (95.7)	
Total	1518 (100.0)	2674 (100.0)	4192 (100.0)	

The denominator was the number of patients in each group within V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ® with at least one dose interval greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not received any rotavirus vaccines.
VE was calculated as one minus the odds ratio for "vaccinated with at least one dose interval greater than 10 weeks".

10.4.1.2 Adjusted Vaccine Effectiveness

Based on univariate logistic regression between RVGE cases and controls (see Table 14.3.4), covariates meeting the $P < 0.1$ for inclusion in the adjusted model were age at onset ($P < 0.001$), residence location (urban vs rural; $P = 0.070$), region of study hospitals (West vs East, $P < 0.001$; Central vs East, $P = 0.064$), clinical setting (inpatient vs outpatient; $P = 0.026$), and symptom onset season (2020/10–2021/03 vs 2024/10–2025/04, $P < 0.001$; 2022/10–2023/04 vs 2024/10–2025/04, $P < 0.001$).

After adjusting for age at onset, residence location, region of study hospitals, clinical setting, and symptom onset season using an unconditional multivariate logistic regression model, the adjusted VE when administered with at least one dose interval >10 weeks was 83.10% (95% CI: 71.03%, 90.14%). Adjusted VE and all model covariate estimates are presented in Table 4 (see also Table 14.3.5).

Table 4. Adjusted vaccine effectiveness against RVGE regardless of type when administered with vaccine dose intervals >10 weeks (Primary Objective Analysis).

Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%, 95% CI)
Age of onset (in months) (Continuous) [1]	0.041	<0.001	1.042 (1.036, 1.047)	
Residence location (Urban vs Rural) [1]	-0.146	0.049	0.865 (0.748, 0.999)	
Regions of study hospitals (Central vs East) [1]	0.295	<0.001	1.343 (1.129, 1.599)	
Regions of study hospitals (West vs East) [1]	0.601	<0.001	1.824 (1.543, 2.155)	
Clinical setting (Inpatient vs Outpatient) [1]	0.703	<0.001	2.019 (1.607, 2.537)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.722	<0.001	5.598 (4.464, 7.019)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	0.159	0.076	1.172 (0.983, 1.397)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-0.679	<0.001	0.507 (0.413, 0.622)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.778	<0.001	0.169 (0.099, 0.290)	83.10% (71.03%, 90.14%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Potential confounders which were significantly different (P < 0.1) between case and controls group were included in model.
[2] Received ROTATEQ® vaccination with at least one dose interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3 was the fixed variable in the logistic regression.
VE was calculated as one minus the odds ratio for "vaccinated with at least one dose interval greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 4190 (including 1516 cases and 2674 controls).

10.4.2 Exploratory Endpoint: Vaccine Effectiveness Against RVGE Due to G1/G2/G3/G4/G9

10.4.2.1 Crude Vaccine Effectiveness

In the exploratory endpoint analysis, 11 children (1.2%, 11/942) in the RVGE case (due to G1/G2/G3/G4/G9) group and 164 (6.1%, 164/2674) in the control group were fully vaccinated with 3 doses of ROTATEQ® with at least one dose interval >10 weeks. The crude VE of ROTATEQ® against RVGE attributable to RV types G1/G2/G3/G4/G9 when administered with at least one dose interval >10 weeks was 81.92% (95% CI: 66.55%, 90.22%). Crude VE is presented in Table 5 (see also Table 14.4.1).

Table 5. Crude vaccine effectiveness against RVGE due to G1/G2/G3/G4/G9 when administered with vaccine dose intervals >10 weeks (Exploratory Objective Analysis).

	Case Group (RV +) N (%)	Control Group (RV -) N (%)	Total N (%)	VE (%, 95% CI)
Vaccinated	11 (1.2)	164 (6.1)	175 (4.8)	81.92% (66.55%, 90.22%)
Unvaccinated	931 (98.8)	2510 (93.9)	3441 (95.2)	
Total	942 (100.0)	2674 (100.0)	3616 (100.0)	

The denominator was the number of patients in each group within V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ® with at least one dose interval greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not received any rotavirus vaccines.
VE was calculated as one minus the odds ratio for "vaccinated with at least one dose interval greater than 10 weeks".

10.4.2.2 Adjusted Vaccine Effectiveness

Based on univariate logistic regression between G1/G2/G3/G4/G9 cases and controls (see Table 14.4.4), covariates meeting the $P < 0.1$ threshold were age at onset ($P < 0.001$), residence location ($P = 0.091$), region of study hospitals (West vs East, $P < 0.001$), and symptom onset season (all three comparisons with 2024/10–2025/04 $P < 0.001$).

After adjusting for age at onset, residence location, region of study hospitals, and symptom onset season using an unconditional multivariate logistic regression model, the adjusted VE when administered with at least one dose interval >10 weeks was 81.73% (95% CI: 64.93%, 90.48%). Adjusted VE and all model covariate estimates are presented in Table 6 (see also Table 14.4.5).

Table 6. Adjusted vaccine effectiveness against RVGE due to G1/G2/G3/G4/G9 when administered with vaccine dose intervals >10 weeks (Exploratory Objective Analysis)

Factors	Regression Coefficient	P Value	OR (95% CI)	VE (%, 95% CI)
Age of onset (in months) (Continuous) [1]	0.036	<0.001	1.037 (1.031, 1.043)	
Residence location (Urban vs Rural) [1]	-0.195	0.032	0.823 (0.689, 0.983)	
Regions of study hospitals (Central vs East) [1]	0.233	0.040	1.262 (1.010, 1.576)	
Regions of study hospitals (West vs East) [1]	0.818	<0.001	2.267 (1.855, 2.770)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.679	<0.001	5.359 (4.251, 6.756)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	-0.874	<0.001	0.417 (0.329, 0.529)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-1.182	<0.001	0.307 (0.238, 0.396)	
Received ROTATEQ® vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.700	<0.001	0.183 (0.095, 0.351)	81.73% (64.93%, 90.48%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Potential confounders which were significantly different ($P < 0.1$) between case and controls group were included in model.
[2] Received ROTATEQ® vaccination with at least one dose interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3 was the fixed variable in the logistic regression.
VE was calculated as one minus the odds ratio for "vaccinated with at least one dose interval greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 3614 (including 940 cases and 2674 controls).

10.4.3 Subgroup Crude Vaccine Effectiveness

10.4.3.1 Subgroup Analyses for the Primary Endpoint

Subgroup analyses of crude VE when administered with at least one dose interval >10 weeks were performed across prespecified demographic and clinical strata for the primary endpoint.

- By age group: Similar VE was observed across age groups (76.08% [95% CI: 22.47%, 92.62%] to 82.56% [95% CI: 66.06%, 91.03%]), with no estimate for 24–35 months due to the absence of vaccinated cases.

- By birth season: VE was higher among children born in the RV peak season (90.33% [95% CI: 76.09%, 96.09%]) than in the non-peak season (76.16% [95% CI: 54.86%, 87.41%]).

- By gender: VE was comparable between males (83.83% [95% CI: 68.88%, 91.60%]) and females (83.49% [95% CI: 61.62%, 92.90%]).

- By residence location: VE was higher in rural (96.75% [95% CI: 76.39%, 99.55%]) than in urban (77.37% [95% CI: 61.02%, 86.86%]) areas.

- By geographic region: VE was generally consistent across regions (79.16% [95% CI: 58.88%, 89.44%] to 91.60% [95% CI: 73.26%, 97.36%]).

- By clinical setting: VE was higher among inpatients (86.86% [95% CI: 76.25%, 92.73%]), whereas the outpatient estimate was lower and imprecise (47.50% [95% CI: −59.58%, 82.73%]) due to the small number of vaccinated cases.

- By symptom onset season: VE ranged from 64.29% (95% CI: −61.10%, 92.08%) to 90.54% (95% CI: 73.90%, 96.57%) across seasons.

Detailed estimates are provided in Table 14.3.2.

10.4.3.2 Subgroup Analyses for the Exploratory Endpoint

Subgroup analyses of crude VE when administer with at least one dose interval >10 weeks against RVGE due to G1/G2/G3/G4/G9 were also performed.

- By age group: VE was 62.46% (95% CI: −22.09%, 88.45%) for ≤11 months, 86.42% (95% CI: 66.22%, 94.54%) for 12–23 months, and 63.84% (95% CI: −27.98%, 89.78%) for ≥36 months; not estimable for 24–35 months (0 vaccinated cases).

- By birth season: VE was 90.65% (95% CI: 70.30%, 97.06%) for the RV peak season and 72.01% (95% CI: 41.56%, 86.59%) for the non-RV peak season.

- By gender: VE was 81.78% (95% CI: 60.57%, 91.58%) for males and 82.18% (95% CI: 50.68%, 93.56%) for females.

- By residence location: VE was 73.06% (95% CI: 49.62%, 85.59%) for urban residence; not estimable for rural residence (0 vaccinated cases).

- By geographic region: VE was 90.28% (95% CI: 60.19%, 97.63%) for Eastern regions, 80.49% (95% CI: 17.99%, 95.36%) for Central regions, and 80.19% (95% CI: 56.22%, 91.04%) for Western regions.

- By clinical setting: VE was 83.86% (95% CI: 68.21%, 91.80%) for inpatients and 62.50% (95% CI: −65.64%, 91.51%) for outpatients.

- By symptom onset season: VE was 60.04% (95% CI: −80.33%, 91.15%) for 2020/10–2021/03, 58.22% (95% CI: −36.07%, 87.17%) for 2021/10–2022/04, 46.32% (95% CI: −76.51%, 83.67%) for 2022/10–2023/04, and 93.74% (95% CI: 74.30%, 98.47%) for 2024/10–2025/04.

  Detailed estimates are provided in Table 14.4.2.

10.4.4 Sensitivity Analysis Results for Primary Endpoint

10.4.4.1 Sensitivity Analysis 1

Sensitivity analysis 1 included children with missing vaccination information, assuming they were unvaccinated. The adjusted VE was 82.83% (95% CI: 70.56%, 89.98%) (see Table 14.5.5).

10.4.4.2 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 83.10% (95% CI: 71.03%, 90.14%) (see Table 14.5.6).

10.4.4.3 Sensitivity Analysis 3

Sensitivity analysis 3 used PSM on age, gender, parents' education, and symptom onset seasons, followed by conditional logistic regression. At 1:1 matching ratio, the adjusted VE was 87.69% (95% CI: 77.39%, 93.30%). At 1:2 matching ratio, the adjusted VE was 84.71% (95% CI: 72.15%, 91.61%). At 1:3 matching ratio, the adjusted VE was 84.51% (95% CI: 71.85%, 91.47%) (see Table 14.5.8.1–14.5.8.3).

10.4.4.4 Sensitivity Analysis 4

Sensitivity analysis 4 used PSM on age, gender, and symptom onset seasons (excluding parents' education), followed by conditional logistic regression. At 1:1 matching ratio, the adjusted VE was 82.59% (95% CI: 70.16%, 89.85%). At 1:2 matching ratio, the adjusted VE was 83.20% (95% CI: 71.49%, 90.10%). At 1:3 matching ratio, the adjusted VE was 82.94% (95% CI: 71.13%, 89.91%) (see Table 14.5.10.1–14.5.10.3).

10.4.4.5 Sensitivity Analysis 5

Sensitivity analysis 5 included parents' education level as an additional covariate in the unconditional multivariate model. The adjusted VE was 85.72% (95% CI: 73.75%, 92.23%) (see Table 14.5.12).

10.4.4.6 Summary of Primary Endpoint Sensitivity Analysis Results

Adjusted VE point estimates against RVGE regardless of type ranged from 82.59% to 87.69% across the 9 sensitivity analysis scenarios evaluated (5 sensitivity analyses with multiple matching ratios for analyses 3 and 4). All estimates remained closely aligned with the primary adjusted VE of 83.10%, and all lower 95% CI bounds exceeded 70%.

10.4.5 Sensitivity Analysis Results for Exploratory Endpoint

Sensitivity analyses for the exploratory endpoint (RVGE due to G1/G2/G3/G4/G9) showed consistent adjusted VE estimates across all scenarios, ranging from 80.46% (95% CI: 62.74%, 89.75%) to 86.13% (95% CI: 70.27%, 93.53%).

The full set of results is available in Table 14.6.5, 14.6.6, 14.6.8.1–14.6.8.3, 14.6.10.1–14.6.10.3, and 14.6.12.

10.4.6 Summary of Sensitivity Analysis Findings

Across all prespecified sensitivity analyses, adjusted VE estimates against RVGE regardless of type ranged from 82.59% to 87.69%, and adjusted VE estimates against RVGE due to G1/G2/G3/G4/G9 ranged from 80.46% to 86.13%. All estimates were statistically significant. Table 7 summarizes the adjusted VE estimates from all sensitivity analyses.

Table 7. Summary of sensitivity analyses: Adjusted VE against RVGE regardless of type (Primary Endpoint Analysis) and RVGE due to G1/G2/G3/G4/G9 (Exploratory Endpoint Analysis) when administered with vaccine dose intervals >10 weeks.

	RVGE regardless of type (%, 95% CI)	RVGE due to G1/G2/G3/G4/G9 (%, 95% CI)
Sensitivity 1	82.83 (70.56, 89.98)	81.45 (64.40, 90.34)
Sensitivity 2	83.10 (71.03, 90.14)	81.73 (64.93, 90.48)
Sensitivity 3-1:1	87.69 (77.39, 93.30)	84.55 (64.48, 93.28)
Sensitivity 3-1:2	84.71 (72.15, 91.61)	86.13 (70.27, 93.53)
Sensitivity 3-1:3	84.51 (71.85, 91.47)	85.96 (70.28, 93.37)
Sensitivity 4-1:1	82.59 (70.16, 89.85)	82.43 (65.93, 90.93)
Sensitivity 4-1:2	83.20 (71.49, 90.10)	80.46 (62.74, 89.75)
Sensitivity 4-1:3	82.94 (71.13, 89.91)	82.37 (66.80, 90.64)
Sensitivity 5	85.72 (73.75, 92.23)	84.55 (67.49, 92.66)

Sensitivity analysis 1: Included participants without confirmed vaccination information in the primary endpoint analysis, assuming that all children with missing vaccination data were unvaccinated.
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 $P \geq 0.1$.
Sensitivity analysis 3: Propensity score matching (PSM) 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), symptom onset seasons. For both primary and exploratory endpoints an up to 1:3 case-to-control PSM ratio was used to allow the utmost of matched pairs, if the number permits.
Sensitivity analysis 4: Propensity score matching followed by conditional logistic regression with matching factors: age of onset (in months), gender, symptom onset seasons. For both primary and exploratory endpoints an up to 1:3 case-to-control PSM ratio was used to allow the utmost of matched pairs, if the number permits.
Sensitivity analysis 5: Included parents' education level into the multivariate model if it differed significantly between cases and controls.

10.5 Safety Results

10.5.1 Scope of Safety Assessment in V260-080

V260-080 leveraged anonymized structured data from V260-077 and focused on VE outcomes; it was not designed to conduct primary safety surveillance or to generate new individual case safety reports for regulatory submission. The analysis focused exclusively on VE outcomes using retrospectively collected data.

10.5.2 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 parent V260-077 surveillance study followed the procedures and reporting mechanisms established in that study protocol, including reporting of serious adverse events within required timeframes.

10.5.3 Safety Conclusion

No adverse event results are presented in this section based on the available V260-080 analysis content. Safety reporting is governed by the pharmacovigilance procedures established for the parent V260-077 study.

11 DISCUSSION

11.1 Key results

Among participants with at least one dose interval >10 weeks, analysis of ROTATEQ® VE showed that extended intervals provided strong protection against RVGE regardless of type and against RVGE attributable to G1/G2/G3/G4/G9 types in Chinese children. The adjusted VE was 83.10% (95% CI: 71.03%, 90.14%) for RVGE regardless of type and 81.73% (95% CI: 64.93%, 90.48%) for RVGE due to G1/G2/G3/G4/G9. The consistency between crude VE (83.70%) and adjusted VE (83.10%) for the primary endpoint indicates that the observed protection was not substantially altered by measured confounders. Sensitivity analyses yielded consistent results across both endpoints, indicating that the estimates were reliable and robust under alternative analytic assumptions. For the primary endpoint, adjusted VE ranged from 82.59% to 87.69% across prespecified sensitivity analyses; for the exploratory endpoint, adjusted VE ranged from 80.46% to 86.13%.

ROTATEQ® in children who had received the vaccine doses with intervals exceeding 10 weeks in this study is consistent with the vaccine efficacy results from post hoc analyses of the global

REST trial, which supported current recommendations in the EMA label and ACIP guidelines, as well as the China expert consensus [Ref. 5.4: 090FC3], [Ref. 5.4: 03RHMM], [Ref. 5.4: 095FH4]. In the REST trial, the primary efficacy analysis included infants vaccinated with dose intervals of at least 4 weeks [Ref. 5.4: 03PZF8]. A post hoc analysis of infants who received a dose more than 10 weeks after the previous dose showed a 100% reduction (95% CI: 60%, 100%) in hospitalization and/or emergency department visits for RVGE regardless of type [Ref. 5.4: 08NPVR].

Real-world studies offer an opportunity to assess VE under real-world conditions and supplement clinical trials, and the findings from this study provide real-world evidence supporting greater flexibility in vaccination strategies for public health, particularly by allowing longer dosing intervals between doses.

11.2 Strengths

This study leveraged the V260-077 database, a MSD-sponsored, large, multicenter post-marketing surveillance 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 broad geographic and temporal representativeness. As a real-world, post-marketing study, V260-077 captures a larger and more heterogeneous population than typical clinical trials during enrollment, including individuals who may not follow protocol-defined vaccination schedules. This enables identification and evaluation of vaccine performance under conditions not commonly observed in controlled trial settings or in larger population, such as those vaccinated with >10 weeks dosing intervals. The V260-077 study employed a central laboratory for RV testing using ELISA and RT-PCR with WHO-recommended testing procedures, consistent with RV surveillance practices in China, the United States, and Europe [Ref. 5.4: 08D7WR], thereby ensuring standardized and reliable outcome ascertainment across all study sites.

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, offering a robust and efficient approach to evaluate vaccine effectiveness in real-world settings by minimizing biases due to different 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 [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]. 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. The analysis further adjusted for key covariates to control potential confounding between cases and controls, and a set of prespecified sensitivity analyses (alternative missing-data assumptions, forced confounder inclusion, propensity score matching with different matching factor sets, and adjustment for parents' education) was used to evaluate the robustness of the primary findings.

Furthermore, this study addressed a critical evidence gap regarding ROTATEQ® administration with longer dosing intervals in Chinese children, providing actionable insights for immunization programs.

11.3 Limitations

As with 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 multivariate 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. 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 scores 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 7510; 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; VE estimates from this sensitivity analysis were consistent with the primary analysis.

As this was a secondary analysis, no a-priori sample size calculation was performed for V260-080, and the results provide effectiveness estimates only for the types that circulated from 2020 to 2025; they cannot be extrapolated to rare types or those that may circulate in the future.

11.4 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 generally 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 may not be 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. 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.

11.5 Public Health Implications

The study addressed a key evidence gap regarding ROTATEQ® administration with longer dosing intervals in Chinese children, as observed in routine practice, providing actionable insights to support increased for more flexibility of longer dosing intervals of thein the immunization schedule. In particular, these results offer a scientific basis for healthcare providers when children are unable to complete vaccination within the 10-week interval limit, supporting continued vaccination rather than discontinuation. This may help ensure completion of the full vaccination series completeness and avoid gaps in protection due to scheduling constraints.

12 CONCLUSION

ROTATEQ® administered with dose intervals >10 weeks provides strong protection against RVGE regardless of type among children in China.

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14 APPENDICES

Table 14.1.1. Analysis datasets

Items	*Total N (%)*
V260-080 Study Population	7510 (100.0)
V260-080 Analysis Population	4192 (55.8)
Reasons for exclusion from V260-080 Analysis Population [1]	3318 (44.2)
Children without vaccination record #	138 (1.8)
Children who had received other RV vaccines than ROTATEQ	1092 (14.5)
Children vaccinated with mixed RV vaccines	7 (0.1)
Children with incomplete ROTATEQ schedule	405 (5.4)
Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	64 (0.9)
Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	1668 (22.2)
Children who had received ROTATEQ within 14 days before the onset of AGE	56 (0.7)
Children with < 4 weeks vaccination intervals	27 (0.4)

The denominator is the number of patients in V260-080 study population.
[1] A patient may have multiple reasons for exclusion from V260-080 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 (V260-080 study population)

Site Number	*Items*	*Total N (%)*
01	V260-080 Study Population	89 (100.0)
	V260-080 Analysis Population	57 (64.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	32 (36.0)
	Children without vaccination record	2 (2.2)
	Children who had received other RV vaccines than ROTATEQ	13 (14.6)
	Children with incomplete ROTATEQ schedule	4 (4.5)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	13 (14.6)
02	V260-080 Study Population	228 (100.0)
	V260-080 Analysis Population	131 (57.5)
	Reasons for exclusion from V260-080 Analysis Population [1]	97 (42.5)
	Children without vaccination record	6 (2.6)
	Children who had received other RV vaccines than ROTATEQ	40 (17.5)
	Children with incomplete ROTATEQ schedule	10 (4.4)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	2 (0.9)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	41 (18.0)
	Children who had received ROTATEQ within 14 days before the onset of AGE	3 (1.3)
	Children with < 4 weeks vaccination intervals	1 (0.4)
03	V260-080 Study Population	332 (100.0)
	V260-080 Analysis Population	207 (62.3)
	Reasons for exclusion from V260-080 Analysis Population [1]	125 (37.7)
	Children without vaccination record	13 (3.9)
	Children who had received other RV vaccines than ROTATEQ	61 (18.4)
	Children with incomplete ROTATEQ schedule	11 (3.3)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	1 (0.3)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	40 (12.0)
04	V260-080 Study Population	107 (100.0)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	V260-080 Analysis Population	64 (59.8)
	Reasons for exclusion from V260-080 Analysis Population [1]	43 (40.2)
	Children without vaccination record	1 (0.9)
	Children who had received other RV vaccines than ROTATEQ	27 (25.2)
	Children with incomplete ROTATEQ schedule	2 (1.9)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	13 (12.1)
05	V260-080 Study Population	77 (100.0)
	V260-080 Analysis Population	47 (61.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	30 (39.0)
	Children who had received other RV vaccines than ROTATEQ	11 (14.3)
	Children with incomplete ROTATEQ schedule	5 (6.5)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	14 (18.2)
	Children with < 4 weeks vaccination intervals	1 (1.3)
06	V260-080 Study Population	230 (100.0)
	V260-080 Analysis Population	127 (55.2)
	Reasons for exclusion from V260-080 Analysis Population [1]	103 (44.8)
	Children without vaccination record	1 (0.4)
	Children who had received other RV vaccines than ROTATEQ	20 (8.7)
	Children with incomplete ROTATEQ schedule	18 (7.8)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	3 (1.3)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	61 (26.5)
	Children who had received ROTATEQ within 14 days before the onset of AGE	5 (2.2)
	Children with < 4 weeks vaccination intervals	1 (0.4)
07	V260-080 Study Population	184 (100.0)
	V260-080 Analysis Population	77 (41.8)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	Reasons for exclusion from V260-080 Analysis Population [1]	107 (58.2)
	Children without vaccination record	1 (0.5)
	Children who had received other RV vaccines than ROTATEQ	40 (21.7)
	Children vaccinated with mixed RV vaccines	1 (0.5)
	Children with incomplete ROTATEQ schedule	16 (8.7)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	51 (27.7)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.5)
08	V260-080 Study Population	623 (100.0)
	V260-080 Analysis Population	444 (71.3)
	Reasons for exclusion from V260-080 Analysis Population [1]	179 (28.7)
	Children without vaccination record	8 (1.3)
	Children who had received other RV vaccines than ROTATEQ	63 (10.1)
	Children vaccinated with mixed RV vaccines	1 (0.2)
	Children with incomplete ROTATEQ schedule	25 (4.0)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	1 (0.2)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	83 (13.3)
	Children who had received ROTATEQ within 14 days before the onset of AGE	2 (0.3)
	Children with < 4 weeks vaccination intervals	1 (0.2)
09	V260-080 Study Population	26 (100.0)
	V260-080 Analysis Population	19 (73.1)
	Reasons for exclusion from V260-080 Analysis Population [1]	7 (26.9)
	Children who had received other RV vaccines than ROTATEQ	5 (19.2)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	2 (7.7)
10	V260-080 Study Population	140 (100.0)
	V260-080 Analysis Population	108 (77.1)
	Reasons for exclusion from V260-080 Analysis Population [1]	32 (22.9)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	Children without vaccination record	2 (1.4)
	Children who had received other RV vaccines than ROTATEQ	5 (3.6)
	Children with incomplete ROTATEQ schedule	4 (2.9)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	1 (0.7)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	21 (15.0)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.7)
	Children with < 4 weeks vaccination intervals	1 (0.7)
11	V260-080 Study Population	429 (100.0)
	V260-080 Analysis Population	253 (59.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	176 (41.0)
	Children without vaccination record	2 (0.5)
	Children who had received other RV vaccines than ROTATEQ	63 (14.7)
	Children with incomplete ROTATEQ schedule	16 (3.7)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	3 (0.7)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	94 (21.9)
	Children who had received ROTATEQ within 14 days before the onset of AGE	4 (0.9)
13	V260-080 Study Population	500 (100.0)
	V260-080 Analysis Population	208 (41.6)
	Reasons for exclusion from V260-080 Analysis Population [1]	292 (58.4)
	Children without vaccination record	10 (2.0)
	Children who had received other RV vaccines than ROTATEQ	148 (29.6)
	Children with incomplete ROTATEQ schedule	30 (6.0)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	7 (1.4)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	100 (20.0)
	Children who had received ROTATEQ within 14 days before the onset of AGE	3 (0.6)
14	V260-080 Study Population	168 (100.0)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	V260-080 Analysis Population	92 (54.8)
	Reasons for exclusion from V260-080 Analysis Population [1]	76 (45.2)
	Children who had received other RV vaccines than ROTATEQ	31 (18.5)
	Children with incomplete ROTATEQ schedule	6 (3.6)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	4 (2.4)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	38 (22.6)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.6)
16	V260-080 Study Population	520 (100.0)
	V260-080 Analysis Population	301 (57.9)
	Reasons for exclusion from V260-080 Analysis Population [1]	219 (42.1)
	Children without vaccination record	5 (1.0)
	Children who had received other RV vaccines than ROTATEQ	73 (14.0)
	Children with incomplete ROTATEQ schedule	17 (3.3)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	6 (1.2)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	123 (23.7)
	Children who had received ROTATEQ within 14 days before the onset of AGE	2 (0.4)
	Children with < 4 weeks vaccination intervals	3 (0.6)
17	V260-080 Study Population	277 (100.0)
	V260-080 Analysis Population	240 (86.6)
	Reasons for exclusion from V260-080 Analysis Population [1]	37 (13.4)
	Children without vaccination record	3 (1.1)
	Children who had received other RV vaccines than ROTATEQ	10 (3.6)
	Children with incomplete ROTATEQ schedule	7 (2.5)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	17 (6.1)
18	V260-080 Study Population	162 (100.0)
	V260-080 Analysis Population	103 (63.6)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	Reasons for exclusion from V260-080 Analysis Population [1]	59 (36.4)
	Children without vaccination record	2 (1.2)
	Children who had received other RV vaccines than ROTATEQ	18 (11.1)
	Children vaccinated with mixed RV vaccines	1 (0.6)
	Children with incomplete ROTATEQ schedule	14 (8.6)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	26 (16.0)
	Children who had received ROTATEQ within 14 days before the onset of AGE	3 (1.9)
19	V260-080 Study Population	29 (100.0)
	V260-080 Analysis Population	23 (79.3)
	Reasons for exclusion from V260-080 Analysis Population [1]	6 (20.7)
	Children without vaccination record	2 (6.9)
	Children who had received other RV vaccines than ROTATEQ	1 (3.4)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	3 (10.3)
20	V260-080 Study Population	177 (100.0)
	V260-080 Analysis Population	66 (37.3)
	Reasons for exclusion from V260-080 Analysis Population [1]	111 (62.7)
	Children without vaccination record	1 (0.6)
	Children who had received other RV vaccines than ROTATEQ	32 (18.1)
	Children with incomplete ROTATEQ schedule	11 (6.2)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	1 (0.6)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	67 (37.9)
	Children who had received ROTATEQ within 14 days before the onset of AGE	6 (3.4)
	Children with < 4 weeks vaccination intervals	1 (0.6)
21	V260-080 Study Population	26 (100.0)
	V260-080 Analysis Population	23 (88.5)
	Reasons for exclusion from V260-080 Analysis Population [1]	3 (11.5)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	Children with incomplete ROTATEQ schedule	2 (7.7)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	1 (3.8)
22	V260-080 Study Population	595 (100.0)
	V260-080 Analysis Population	257 (43.2)
	Reasons for exclusion from V260-080 Analysis Population [1]	338 (56.8)
	Children without vaccination record	22 (3.7)
	Children who had received other RV vaccines than ROTATEQ	86 (14.5)
	Children vaccinated with mixed RV vaccines	3 (0.5)
	Children with incomplete ROTATEQ schedule	66 (11.1)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	2 (0.3)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	166 (27.9)
	Children who had received ROTATEQ within 14 days before the onset of AGE	9 (1.5)
	Children with < 4 weeks vaccination intervals	7 (1.2)
23	V260-080 Study Population	263 (100.0)
	V260-080 Analysis Population	118 (44.9)
	Reasons for exclusion from V260-080 Analysis Population [1]	145 (55.1)
	Children without vaccination record	9 (3.4)
	Children who had received other RV vaccines than ROTATEQ	56 (21.3)
	Children with incomplete ROTATEQ schedule	10 (3.8)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	1 (0.4)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	71 (27.0)
24	V260-080 Study Population	277 (100.0)
	V260-080 Analysis Population	122 (44.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	155 (56.0)
	Children without vaccination record	11 (4.0)
	Children who had received other RV vaccines than ROTATEQ	50 (18.1)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	Children with incomplete ROTATEQ schedule	8 (2.9)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	5 (1.8)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	83 (30.0)
	Children with < 4 weeks vaccination intervals	1 (0.4)
25	V260-080 Study Population	667 (100.0)
	V260-080 Analysis Population	324 (48.6)
	Reasons for exclusion from V260-080 Analysis Population [1]	343 (51.4)
	Children without vaccination record	15 (2.2)
	Children who had received other RV vaccines than ROTATEQ	47 (7.0)
	Children with incomplete ROTATEQ schedule	28 (4.2)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	12 (1.8)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	248 (37.2)
	Children who had received ROTATEQ within 14 days before the onset of AGE	5 (0.7)
	Children with < 4 weeks vaccination intervals	4 (0.6)
26	V260-080 Study Population	7 (100.0)
	V260-080 Analysis Population	4 (57.1)
	Reasons for exclusion from V260-080 Analysis Population [1]	3 (42.9)
	Children who had received other RV vaccines than ROTATEQ	2 (28.6)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	1 (14.3)
28	V260-080 Study Population	520 (100.0)
	V260-080 Analysis Population	309 (59.4)
	Reasons for exclusion from V260-080 Analysis Population [1]	211 (40.6)
	Children without vaccination record	17 (3.3)
	Children who had received other RV vaccines than ROTATEQ	62 (11.9)
	Children with incomplete ROTATEQ schedule	46 (8.8)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	6 (1.2)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	88 (16.9)
	Children who had received ROTATEQ within 14 days before the onset of AGE	7 (1.3)
	Children with < 4 weeks vaccination intervals	1 (0.2)
29	V260-080 Study Population	197 (100.0)
	V260-080 Analysis Population	94 (47.7)
	Reasons for exclusion from V260-080 Analysis Population [1]	103 (52.3)
	Children without vaccination record	1 (0.5)
	Children who had received other RV vaccines than ROTATEQ	39 (19.8)
	Children with incomplete ROTATEQ schedule	11 (5.6)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	3 (1.5)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	50 (25.4)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (0.5)
	Children with < 4 weeks vaccination intervals	1 (0.5)
30	V260-080 Study Population	91 (100.0)
	V260-080 Analysis Population	47 (51.6)
	Reasons for exclusion from V260-080 Analysis Population [1]	44 (48.4)
	Children without vaccination record	1 (1.1)
	Children who had received other RV vaccines than ROTATEQ	4 (4.4)
	Children vaccinated with mixed RV vaccines	1 (1.1)
	Children with incomplete ROTATEQ schedule	4 (4.4)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	36 (39.6)
	Children with < 4 weeks vaccination intervals	2 (2.2)
31	V260-080 Study Population	3 (100.0)
	V260-080 Analysis Population	2 (66.7)
	Reasons for exclusion from V260-080 Analysis Population [1]	1 (33.3)
	Children who had received other RV vaccines than ROTATEQ	1 (33.3)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
33	V260-080 Study Population	136 (100.0)
	V260-080 Analysis Population	81 (59.6)
	Reasons for exclusion from V260-080 Analysis Population [1]	55 (40.4)
	Children without vaccination record	2 (1.5)
	Children who had received other RV vaccines than ROTATEQ	23 (16.9)
	Children with incomplete ROTATEQ schedule	8 (5.9)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	22 (16.2)
	Children who had received ROTATEQ within 14 days before the onset of AGE	2 (1.5)
	Children with < 4 weeks vaccination intervals	1 (0.7)
34	V260-080 Study Population	14 (100.0)
	V260-080 Analysis Population	7 (50.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	7 (50.0)
	Children who had received other RV vaccines than ROTATEQ	4 (28.6)
	Children with incomplete ROTATEQ schedule	2 (14.3)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	1 (7.1)
37	V260-080 Study Population	61 (100.0)
	V260-080 Analysis Population	33 (54.1)
	Reasons for exclusion from V260-080 Analysis Population [1]	28 (45.9)
	Children without vaccination record	1 (1.6)
	Children who had received other RV vaccines than ROTATEQ	7 (11.5)
	Children with incomplete ROTATEQ schedule	2 (3.3)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	2 (3.3)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	16 (26.2)
	Children who had received ROTATEQ within 14 days before the onset of AGE	1 (1.6)
38	V260-080 Study Population	59 (100.0)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
	V260-080 Analysis Population	37 (62.7)
	Reasons for exclusion from V260-080 Analysis Population [1]	22 (37.3)
	Children who had received other RV vaccines than ROTATEQ	11 (18.6)
	Children with incomplete ROTATEQ schedule	3 (5.1)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	8 (13.6)
39	V260-080 Study Population	65 (100.0)
	V260-080 Analysis Population	26 (40.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	39 (60.0)
	Children who had received other RV vaccines than ROTATEQ	10 (15.4)
	Children with incomplete ROTATEQ schedule	3 (4.6)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	3 (4.6)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	25 (38.5)
	Children with < 4 weeks vaccination intervals	1 (1.5)
40	V260-080 Study Population	108 (100.0)
	V260-080 Analysis Population	77 (71.3)
	Reasons for exclusion from V260-080 Analysis Population [1]	31 (28.7)
	Children who had received other RV vaccines than ROTATEQ	16 (14.8)
	Children with incomplete ROTATEQ schedule	9 (8.3)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	6 (5.6)
41	V260-080 Study Population	40 (100.0)
	V260-080 Analysis Population	32 (80.0)
	Reasons for exclusion from V260-080 Analysis Population [1]	8 (20.0)
	Children who had received other RV vaccines than ROTATEQ	1 (2.5)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	7 (17.5)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.1.2. Analysis datasets for each site (V260-080 study population) *(Continued)*

Site Number	*Items*	*Total N (%)*
42	V260-080 Study Population	23 (100.0)
	V260-080 Analysis Population	16 (69.6)
	Reasons for exclusion from V260-080 Analysis Population [1]	7 (30.4)
	Children with incomplete ROTATEQ schedule	2 (8.7)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	5 (21.7)
43	V260-080 Study Population	60 (100.0)
	V260-080 Analysis Population	16 (26.7)
	Reasons for exclusion from V260-080 Analysis Population [1]	44 (73.3)
	Children who had received other RV vaccines than ROTATEQ	12 (20.0)
	Children with incomplete ROTATEQ schedule	5 (8.3)
	Children vaccinated out of age-indication (age-indication defined as the first dose to be administered at age 6 to 12 weeks and the third dose at no later than 32 weeks of age)	1 (1.7)
	Children with both vaccine dose intervals <= 10 weeks of ROTATEQ	27 (45.0)

The denominator is the number of patients in V260-080 study population by site.
[1] A patient may have multiple reasons for exclusion from V260-080 analysis population.

Table 14.2.1. Demographic characteristics (V260-080 study and analysis population)

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
Age at the time of signing ICF (months)	n (nmiss)	7510 (0)	4192 (0)
	Mean (Std)	20.12 (13.495)	20.00 (13.507)
	Median	16.30	16.10
	Q1, Q3	10.80, 25.00	10.80, 24.50
	Min, Max	3.7, 79.8	3.7, 78.0
Gender (n, %)	Male	4550 (60.6)	2565 (61.2)
	Female	2960 (39.4)	1627 (38.8)
	Total	7510 (100.0)	4192 (100.0)
Residence location (n, %)	Urban	4904 (65.3)	2610 (62.3)
	Rural	2600 (34.6)	1580 (37.7)
	Missing	6 (0.1)	2 (0.05)
	Total	7510 (100.0)	4192 (100.0)
Education level of the children's father (n, %)	Illiteracy	12 (0.2)	10 (0.2)
	Primary school	109 (1.5)	77 (1.8)
	Junior school	865 (11.5)	529 (12.6)
	Senior school	1410 (18.8)	846 (20.2)
	College	3781 (50.3)	1886 (45.0)
	Master	230 (3.1)	74 (1.8)
	Doctor	18 (0.2)	8 (0.2)
	Missing	1085 (14.4)	762 (18.2)
	Total	7510 (100.0)	4192 (100.0)
Education level of the children's mother (n, %)	Illiteracy	12 (0.2)	9 (0.2)
	Primary school	123 (1.6)	85 (2.0)
	Junior school	868 (11.6)	547 (13.0)
	Senior school	1373 (18.3)	829 (19.8)
	College	4008 (53.4)	1969 (47.0)
	Master	188 (2.5)	61 (1.5)
	Doctor	9 (0.1)	3 (0.1)

The denominator is the number of patients in V260-080 study or analysis population, respectively.
nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

Table 14.2.1. Demographic characteristics (V260-080 study and analysis population) *(Continued)*

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
	Missing	929 (12.4)	689 (16.4)
	Total	7510 (100.0)	4192 (100.0)
College and above for either parent's education level (n, %)	No	2003 (26.7)	1258 (30.0)
	Yes	4649 (61.9)	2288 (54.6)
	Missing	858 (11.4)	646 (15.4)
	Total	7510 (100.0)	4192 (100.0)

The denominator is the number of patients in V260-080 study or analysis population, respectively.
nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.

Table 14.2.2. Characteristic of AGE cases at enrollment (V260-080 study and analysis population)

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
Age of onset (in weeks)	n (nmiss)	7510 (0)	4192 (0)
	Mean (Std)	87.01 (58.725)	86.48 (58.774)
	Median	70.60	69.40
	Q1, Q3	46.40, 108.10	46.65, 105.80
	Min, Max	16.0, 346.7	16.1, 339.0
Age of onset (in months)	n (nmiss)	7510 (0)	4192 (0)
	Mean (Std)	20.01 (13.506)	19.89 (13.518)
	Median	16.20	16.00
	Q1, Q3	10.70, 24.90	10.70, 24.30
	Min, Max	3.7, 79.7	3.7, 78.0
Age of onset group (n, %)	<=11 months	2292 (30.5)	1272 (30.3)
	12-23 months	3197 (42.6)	1835 (43.8)
	24-35 months	1111 (14.8)	582 (13.9)
	>=36 months	910 (12.1)	503 (12.0)
	Total	7510 (100.0)	4192 (100.0)
Had diarrhea before visiting the hospital (n, %)	Yes	7510 (100.0)	4192 (100.0)
	Total	7510 (100.0)	4192 (100.0)
Number of days of diarrhea before visiting the hospital	n (nmiss)	7510 (0)	4192 (0)
	Mean (Std)	3.25 (2.264)	3.26 (2.257)
	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 V260-080 study 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 2399 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

Table 14.2.2. Characteristic of AGE cases at enrollment (V260-080 study and analysis population) *(Continued)*

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
Maximum number of stools per day before visiting the hospital	n (nmiss)	7510 (0)	4192 (0)
	Mean (Std)	6.06 (3.157)	6.19 (3.212)
	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)	2732 (65.2)
	Bloody	276 (3.7)	134 (3.2)
	Rice washed	15 (0.2)	8 (0.2)
	Others	3421 (45.6)	1798 (42.9)
Had vomiting before visiting the hospital (n, %)[3]	No	3220 (42.9)	1591 (38.0)
	Yes	3967 (52.8)	2399 (57.2)
	Missing	323 (4.3)	202 (4.8)
	Total	7510 (100.0)	4192 (100.0)
Number of days of vomiting before visiting the hospital[4]	n (nmiss)	3967 (0)	2399 (0)
	Mean (Std)	2.44 (1.637)	2.50 (1.673)
	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)	2110 (289)
	Mean (Std)	4.72 (3.424)	5.02 (3.541)
	Median	4.00	4.00

The denominator is the number of patients in V260-080 study 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 2399 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

Table 14.2.2. Characteristic of AGE cases at enrollment (V260-080 study and analysis population) *(Continued)*

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
	Q1, Q3	2.00, 6.00	3.00, 7.00
	Min, Max	1.0, 30.0	1.0, 30.0
Vomit characteristic (n, %)[2][4]	Gastric contents	3786 (95.4)	2291 (95.5)
	Water samples	56 (1.4)	39 (1.6)
	Bloody vomit	16 (0.4)	8 (0.3)
	Others	252 (6.4)	153 (6.4)
Axillary temperature has been measured before visiting the hospital (n, %)	No	1642 (21.9)	863 (20.6)
	Yes	5868 (78.1)	3329 (79.4)
	Total	7510 (100.0)	4192 (100.0)
Highest axillary temperature before visiting the hospital (℃)	n (nmiss)	5862 (6)	3325 (4)
	Mean (Std)	38.31 (1.288)	38.35 (1.254)
	Median	38.50	38.50
	Q1, Q3	37.00, 39.30	37.10, 39.30
	Min, Max	36.0, 42.0	36.0, 42.0
Received oral rehydration before visiting the hospital (n, %)	No	5627 (74.9)	3115 (74.3)
	Yes	1134 (15.1)	622 (14.8)
	Missing	749 (10.0)	455 (10.9)
	Total	7510 (100.0)	4192 (100.0)
Total number of days of oral rehydration before visiting the hospital	n (nmiss)	1134 (0)	622 (0)
	Mean (Std)	1.80 (1.192)	1.85 (1.306)
	Median	1.00	1.00

The denominator is the number of patients in V260-080 study 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 2399 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

Table 14.2.2. Characteristic of AGE cases at enrollment (V260-080 study and analysis population) *(Continued)*

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
	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)	2625 (62.6)
	Yes	2077 (27.7)	1215 (29.0)
	Missing	564 (7.5)	352 (8.4)
	Total	7510 (100.0)	4192 (100.0)
Total number of days of intravenous fluid rehydration before visiting the hospital	n (nmiss)	2077 (0)	1215 (0)
	Mean (Std)	1.79 (1.220)	1.86 (1.342)
	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 V260-080 study 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 2399 for analysis population), and corresponding variable records from patients with missing vomiting status were not included in the analysis.

Table 14.2.3. Treatment of AGE (V260-080 study and analysis population)

		V260-080 Study Population (N=7510)	*V260-080 Analysis Population (N=4192)*
Child admitted to the inpatient ward (n, %)	No	969 (12.9)	516 (12.3)
	Yes	6541 (87.1)	3676 (87.7)
	Total	7510 (100.0)	4192 (100.0)
Child received fluid rehydration treatment (n, %) [1]	Intravenous fluids	7162 (95.4)	4015 (95.8)
	Oral rehydration	2270 (30.2)	1269 (30.3)
	Nothing	258 (3.4)	121 (2.9)
Number of days of intravenous fluid required by the doctor for the child treated with intravenous fluids	n (nmiss)	7121 (41)	3986 (29)
	Mean (Std)	3.4 (1.89)	3.5 (1.88)
	Median	3.0	3.0
	Q1, Q3	2.0, 4.0	2.0, 5.0
	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)	1207 (62)
	Mean (Std)	3.2 (1.90)	3.1 (1.91)
	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 V260-080 study or analysis population, respectively.
nmiss = number of patients with missing data; Std = standard deviation; Q1 and Q3 = interquartile range.
[1] A patient may have selected both intravenous fluid and oral rehydration.

Table 14.2.4. Vaccination status (V260-080 analysis population)

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (All sites)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	180 (4.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	2 (0.05)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	70 (1.7)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	108 (2.6)
	Unvaccinated	4012 (95.7)
	Total	4192 (100.0)
Rotavirus vaccination (site 01)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (1.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (1.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	56 (98.2)
	Total	57 (100.0)
Rotavirus vaccination (site 02)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	4 (3.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	2 (1.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	2 (1.5)
	Unvaccinated	127 (96.9)
	Total	131 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 03)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	3 (1.4)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (0.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	2 (1.0)
	Unvaccinated	204 (98.6)
	Total	207 (100.0)
Rotavirus vaccination (site 04)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	64 (100.0)
	Total	64 (100.0)
Rotavirus vaccination (site 05)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	9 (19.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	2 (4.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	7 (14.9)
	Unvaccinated	38 (80.9)
	Total	47 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 06)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	4 (3.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (0.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	3 (2.4)
	Unvaccinated	123 (96.9)
	Total	127 (100.0)
Rotavirus vaccination (site 07)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (1.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (1.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	76 (98.7)
	Total	77 (100.0)
Rotavirus vaccination (site 08)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	10 (2.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (0.2)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	6 (1.4)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	3 (0.7)
	Unvaccinated	434 (97.7)
	Total	444 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 09)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (5.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (5.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	18 (94.7)
	Total	19 (100.0)
Rotavirus vaccination (site 10)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	3 (2.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	3 (2.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	105 (97.2)
	Total	108 (100.0)
Rotavirus vaccination (site 11)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	8 (3.2)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	2 (0.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	6 (2.4)
	Unvaccinated	245 (96.8)
	Total	253 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 13)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	32 (15.4)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	10 (4.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	22 (10.6)
	Unvaccinated	176 (84.6)
	Total	208 (100.0)
Rotavirus vaccination (site 14)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	2 (2.2)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (1.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (1.1)
	Unvaccinated	90 (97.8)
	Total	92 (100.0)
Rotavirus vaccination (site 16)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	18 (6.0)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	5 (1.7)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	13 (4.3)
	Unvaccinated	283 (94.0)
	Total	301 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 17)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	240 (100.0)
	Total	240 (100.0)
Rotavirus vaccination (site 18)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	9 (8.7)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (1.0)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	2 (1.9)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	6 (5.8)
	Unvaccinated	94 (91.3)
	Total	103 (100.0)
Rotavirus vaccination (site 19)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	23 (100.0)
	Total	23 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 20)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (1.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (1.5)
	Unvaccinated	65 (98.5)
	Total	66 (100.0)
Rotavirus vaccination (site 21)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (4.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (4.3)
	Unvaccinated	22 (95.7)
	Total	23 (100.0)
Rotavirus vaccination (site 22)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	13 (5.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	6 (2.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	7 (2.7)
	Unvaccinated	244 (94.9)
	Total	257 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 23)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	8 (6.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	4 (3.4)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	4 (3.4)
	Unvaccinated	110 (93.2)
	Total	118 (100.0)
Rotavirus vaccination (site 24)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	4 (3.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	3 (2.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (0.8)
	Unvaccinated	118 (96.7)
	Total	122 (100.0)
Rotavirus vaccination (site 25)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	18 (5.6)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	8 (2.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	10 (3.1)
	Unvaccinated	306 (94.4)
	Total	324 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 26)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	4 (100.0)
	Total	4 (100.0)
Rotavirus vaccination (site 28)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	10 (3.2)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	2 (0.6)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	8 (2.6)
	Unvaccinated	299 (96.8)
	Total	309 (100.0)
Rotavirus vaccination (site 29)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	9 (9.6)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	3 (3.2)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	6 (6.4)
	Unvaccinated	85 (90.4)
	Total	94 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 30)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	2 (4.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	2 (4.3)
	Unvaccinated	45 (95.7)
	Total	47 (100.0)
Rotavirus vaccination (site 31)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	2 (100.0)
	Total	2 (100.0)
Rotavirus vaccination (site 33)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	81 (100.0)
	Total	81 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 34)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	7 (100.0)
	Total	7 (100.0)
Rotavirus vaccination (site 37)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (3.0)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (3.0)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	32 (97.0)
	Total	33 (100.0)
Rotavirus vaccination (site 38)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	37 (100.0)
	Total	37 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 39)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (3.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (3.8)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	25 (96.2)
	Total	26 (100.0)
Rotavirus vaccination (site 40)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	2 (2.6)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (1.3)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	1 (1.3)
	Unvaccinated	75 (97.4)
	Total	77 (100.0)
Rotavirus vaccination (site 41)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	1 (3.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	1 (3.1)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	31 (96.9)
	Total	32 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.4. Vaccination status (V260-080 analysis population) *(Continued)*

		V260-080 Analysis Population (N=4192)
Rotavirus vaccination (site 42)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	2 (12.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	2 (12.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Unvaccinated	14 (87.5)
	Total	16 (100.0)
Rotavirus vaccination (site 43)	Fully vaccinated with ROTATEQ with at least one dosing interval greater than 10 weeks between doses 1 and 2 and/or 2 and 3	2 (12.5)
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 > 10 weeks, and interval between dose 2 and dose 3 <= 10 weeks)	0
	Fully vaccinated with ROTATEQ (interval between dose 1 and dose 2 <= 10 weeks, and interval between dose 2 and dose 3 > 10 weeks)	2 (12.5)
	Unvaccinated	14 (87.5)
	Total	16 (100.0)

The denominator is the number of patients in V260-080 analysis population by site.

Table 14.2.5. Rotavirus detection and typing results (V260-080 analysis population)

Symptom onset seasons			*V260-080 Analysis Population (N=4192)*
Symptom onset seasons: Total	ELISA testing results (n, %) [1]	Positive	1518 (36.2)
		Negative	2674 (63.8)
		Total	4192 (100.0)
	VP7(G type) results (n, %) [2]	G1	17 (1.1)
		G2	51 (3.4)
		G3	233 (15.3)
		G4	3 (0.2)
		G6	2 (0.1)
		G8	530 (34.9)
		G9	638 (42.0)
		G11	1 (0.1)
		G12	1 (0.1)
		G non-typable	42 (2.8)
		Total	1518 (100.0)
	VP4(P type) results (n, %) [2]	P[4]	60 (4.0)
		P[6]	3 (0.2)
		P[8]	1421 (93.6)
		P[9]	5 (0.3)
		P non-typable	29 (1.9)
		Total	1518 (100.0)
Symptom onset seasons: 2020/10-2021/3	ELISA testing results (n, %) [3]	Positive	415 (67.5)
		Negative	200 (32.5)
		Total	615 (100.0)
	VP7(G type) results (n, %) [4]	G1	0
		G2	21 (5.1)
		G3	1 (0.2)

[1] The denominator is the number of patients in V260-080 analysis population.
[2] The denominator is the number of patients with ELISA positive results.
[3] The denominator is the number of patients in V260-080 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 (V260-080 analysis population) *(Continued)*

Symptom onset seasons			*V260-080 Analysis Population (N=4192)*
		G4	0
		G6	0
		G8	17 (4.1)
		G9	349 (84.1)
		G11	0
		G12	0
		G non-typable	27 (6.5)
		Total	415 (100.0)
	VP4(P type) results (n, %) [4]	P[4]	22 (5.3)
		P[6]	0
		P[8]	374 (90.1)
		P[9]	0
		P non-typable	19 (4.6)
		Total	415 (100.0)
Symptom onset seasons: 2021/10-2022/4	ELISA testing results (n, %) [3]	Positive	446 (33.3)
		Negative	895 (66.7)
		Total	1341 (100.0)
	VP7(G type) results (n, %) [4]	G1	6 (1.3)
		G2	8 (1.8)
		G3	5 (1.1)
		G4	1 (0.2)
		G6	0
		G8	310 (69.5)
		G9	107 (24.0)
		G11	0
		G12	0
		G non-typable	9 (2.0)

[1] The denominator is the number of patients in V260-080 analysis population.
[2] The denominator is the number of patients with ELISA positive results.
[3] The denominator is the number of patients in V260-080 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 (V260-080 analysis population) *(Continued)*

Symptom onset seasons			*V260-080 Analysis Population (N=4192)*
		Total	446 (100.0)
	VP4(P type) results (n, %) [4]	P[4]	9 (2.0)
		P[6]	1 (0.2)
		P[8]	430 (96.4)
		P[9]	3 (0.7)
		P non-typable	3 (0.7)
		Total	446 (100.0)
Symptom onset seasons: 2022/10-2023/4	ELISA testing results (n, %) [3]	Positive	200 (20.6)
		Negative	771 (79.4)
		Total	971 (100.0)
	VP7(G type) results (n, %) [4]	G1	6 (3.0)
		G2	14 (7.0)
		G3	11 (5.5)
		G4	1 (0.5)
		G6	1 (0.5)
		G8	98 (49.0)
		G9	68 (34.0)
		G11	0
		G12	0
		G non-typable	1 (0.5)
		Total	200 (100.0)
	VP4(P type) results (n, %) [4]	P[4]	23 (11.5)
		P[6]	1 (0.5)
		P[8]	173 (86.5)
		P[9]	1 (0.5)
		P non-typable	2 (1.0)

[1] The denominator is the number of patients in V260-080 analysis population.
[2] The denominator is the number of patients with ELISA positive results.
[3] The denominator is the number of patients in V260-080 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 (V260-080 analysis population) *(Continued)*

Symptom onset seasons			*V260-080 Analysis Population (N=4192)*
		Total	200 (100.0)
Symptom onset seasons: 2024/10-2025/4	ELISA testing results (n, %) [3]	Positive	457 (36.1)
		Negative	808 (63.9)
		Total	1265 (100.0)
	VP7(G type) results (n, %) [4]	G1	5 (1.1)
		G2	8 (1.8)
		G3	216 (47.3)
		G4	1 (0.2)
		G6	1 (0.2)
		G8	105 (23.0)
		G9	114 (24.9)
		G11	1 (0.2)
		G12	1 (0.2)
		G non-typable	5 (1.1)
		Total	457 (100.0)
	VP4(P type) results (n, %) [4]	P[4]	6 (1.3)
		P[6]	1 (0.2)
		P[8]	444 (97.2)
		P[9]	1 (0.2)
		P non-typable	5 (1.1)
		Total	457 (100.0)

[1] The denominator is the number of patients in V260-080 analysis population.
[2] The denominator is the number of patients with ELISA positive results.
[3] The denominator is the number of patients in V260-080 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 types classified by G-P type combinations-Total symptom onset seasons (V260-080 analysis population)

Types	*P[4]*	*P[6]*	*P[8]*	*P[9]*	*Other P-type*	*P non-typable*	*Total*
G1	0	0	17 (1.1)	0	0	0	17 (1.1)
G2	48 (3.2)	0	2 (0.1)	0	0	1 (0.1)	51 (3.4)
G3	0	0	227 (15.0)	5 (0.3)	0	1 (0.1)	233 (15.3)
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	528 (34.8)	0	0	2 (0.1)	530 (34.9)
G9	8 (0.5)	0	626 (41.2)	0	0	4 (0.3)	638 (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	19 (1.3)	42 (2.8)
Total	60 (4.0)	3 (0.2)	1421 (93.6)	5 (0.3)	0	29 (1.9)	1518 (100.0)

The denominator is the number of patients from the V260-080 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 (V260-080 analysis population)

Types	*P[4]*	*P[6]*	*P[8]*	*P[9]*	*Other P-type*	*P non-typable*	*Total*
G1	0	0	0	0	0	0	0
G2	20 (4.8)	0	0	0	0	1 (0.2)	21 (5.1)
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	17 (4.1)	0	0	0	17 (4.1)
G9	0	0	347 (83.6)	0	0	2 (0.5)	349 (84.1)
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	2 (0.5)	0	9 (2.2)	0	0	16 (3.9)	27 (6.5)
Total	22 (5.3)	0	374 (90.1)	0	0	19 (4.6)	415 (100.0)

The denominator is the number of patients from the V260-080 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 14.2.8. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2021/10-2022/4 (V260-080 analysis population)

Types	*P[4]*	*P[6]*	*P[8]*	*P[9]*	*Other P-type*	*P non-typable*	*Total*
G1	0	0	6 (1.3)	0	0	0	6 (1.3)
G2	8 (1.8)	0	0	0	0	0	8 (1.8)
G3	0	0	2 (0.4)	3 (0.7)	0	0	5 (1.1)
G4	0	1 (0.2)	0	0	0	0	1 (0.2)
G6	0	0	0	0	0	0	0
G8	0	0	309 (69.3)	0	0	1 (0.2)	310 (69.5)
G9	0	0	107 (24.0)	0	0	0	107 (24.0)
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 (1.3)	0	0	2 (0.4)	9 (2.0)
Total	9 (2.0)	1 (0.2)	430 (96.4)	3 (0.7)	0	3 (0.7)	446 (100.0)

The denominator is the number of patients from the V260-080 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 14.2.9. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2022/10-2023/4 (V260-080 analysis population)

Types	*P[4]*	*P[6]*	*P[8]*	*P[9]*	*Other P-type*	*P non-typable*	*Total*
G1	0	0	6 (3.0)	0	0	0	6 (3.0)
G2	14 (7.0)	0	0	0	0	0	14 (7.0)
G3	0	0	10 (5.0)	1 (0.5)	0	0	11 (5.5)
G4	0	1 (0.5)	0	0	0	0	1 (0.5)
G6	0	0	0	0	0	1 (0.5)	1 (0.5)
G8	0	0	98 (49.0)	0	0	0	98 (49.0)
G9	8 (4.0)	0	59 (29.5)	0	0	1 (0.5)	68 (34.0)
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 (0.5)	0	0	0	0	0	1 (0.5)
Total	23 (11.5)	1 (0.5)	173 (86.5)	1 (0.5)	0	2 (1.0)	200 (100.0)

The denominator is the number of patients from the V260-080 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 14.2.10. Frequency of Rotavirus A types classified by G-P type combinations-Symptom onset season: 2024/10-2025/4 (V260-080 analysis population)

Types	*P[4]*	*P[6]*	*P[8]*	*P[9]*	*Other P-type*	*P non-typable*	*Total*
G1	0	0	5 (1.1)	0	0	0	5 (1.1)
G2	6 (1.3)	0	2 (0.4)	0	0	0	8 (1.8)
G3	0	0	214 (46.8)	1 (0.2)	0	1 (0.2)	216 (47.3)
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	104 (22.8)	0	0	1 (0.2)	105 (23.0)
G9	0	0	113 (24.7)	0	0	1 (0.2)	114 (24.9)
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 (0.9)	0	0	1 (0.2)	5 (1.1)
Total	6 (1.3)	1 (0.2)	444 (97.2)	1 (0.2)	0	5 (1.1)	457 (100.0)

The denominator is the number of patients from the V260-080 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 14.3.1. Crude vaccine effectiveness against RVGE cases (V260-080 analysis population)

	Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Vaccinated	16 (1.1)	164 (6.1)	180 (4.3)	83.70% (72.65%, 90.28%)
Unvaccinated	1502 (98.9)	2510 (93.9)	4012 (95.7)	
Total	1518 (100.0)	2674 (100.0)	4192 (100.0)	

The denominator is the number of patients in each group within V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not received any rotavirus vaccines.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".

Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (V260-080 analysis population)

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Age of onset group	<=11 months	Vaccinated	3 (1.1)	46 (4.6)	49 (3.9)	76.08% (22.47%, 92.62%)
		Unvaccinated	262 (98.9)	961 (95.4)	1223 (96.1)	
		Total	265 (100.0)	1007 (100.0)	1272 (100.0)	
	12-23 months	Vaccinated	10 (1.3)	77 (7.1)	87 (4.7)	82.56% (66.06%, 91.03%)
		Unvaccinated	746 (98.7)	1002 (92.9)	1748 (95.3)	
		Total	756 (100.0)	1079 (100.0)	1835 (100.0)	
	24-35 months	Vaccinated	0	27 (8.2)	27 (4.6)	NA*
		Unvaccinated	251 (100.0)	304 (91.8)	555 (95.4)	
		Total	251 (100.0)	331 (100.0)	582 (100.0)	
	>=36 months	Vaccinated	3 (1.2)	14 (5.4)	17 (3.4)	78.57% (24.48%, 93.92%)
		Unvaccinated	243 (98.8)	243 (94.6)	486 (96.6)	
		Total	246 (100.0)	257 (100.0)	503 (100.0)	
Birth seasons	RV peak season [1]	Vaccinated	5 (0.6)	85 (5.6)	90 (3.7)	90.33% (76.09%, 96.09%)
		Unvaccinated	879 (99.4)	1444 (94.4)	2323 (96.3)	
		Total	884 (100.0)	1529 (100.0)	2413 (100.0)	
	Non-RV peak season	Vaccinated	11 (1.7)	79 (6.9)	90 (5.1)	76.16% (54.86%, 87.41%)
		Unvaccinated	623 (98.3)	1066 (93.1)	1689 (94.9)	
		Total	634 (100.0)	1145 (100.0)	1779 (100.0)	
Residence location	Urban	Vaccinated	15 (1.6)	116 (6.9)	131 (5.0)	77.37% (61.02%, 86.86%)
		Unvaccinated	902 (98.4)	1577 (93.1)	2479 (95.0)	
		Total	917 (100.0)	1693 (100.0)	2610 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (V260-080 analysis population) *(Continued)*

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
	Rural	Vaccinated	1 (0.2)	48 (4.9)	49 (3.1)	96.75% (76.39%, 99.55%)
		Unvaccinated	598 (99.8)	933 (95.1)	1531 (96.9)	
		Total	599 (100.0)	981 (100.0)	1580 (100.0)	
Regions of study hospitals [2]	East	Vaccinated	3 (0.5)	71 (5.5)	74 (3.9)	91.60% (73.26%, 97.36%)
		Unvaccinated	619 (99.5)	1228 (94.5)	1847 (96.1)	
		Total	622 (100.0)	1299 (100.0)	1921 (100.0)	
	Central	Vaccinated	3 (0.8)	33 (4.9)	36 (3.4)	84.31% (48.51%, 95.22%)
		Unvaccinated	375 (99.2)	647 (95.1)	1022 (96.6)	
		Total	378 (100.0)	680 (100.0)	1058 (100.0)	
	West	Vaccinated	10 (1.9)	60 (8.6)	70 (5.8)	79.16% (58.88%, 89.44%)
		Unvaccinated	508 (98.1)	635 (91.4)	1143 (94.2)	
		Total	518 (100.0)	695 (100.0)	1213 (100.0)	
Clinical setting	Inpatient	Vaccinated	12 (0.9)	148 (6.4)	160 (4.4)	86.86% (76.25%, 92.73%)
		Unvaccinated	1342 (99.1)	2174 (93.6)	3516 (95.6)	
		Total	1354 (100.0)	2322 (100.0)	3676 (100.0)	
	Outpatient	Vaccinated	4 (2.4)	16 (4.5)	20 (3.9)	47.50% (-59.58%, 82.73%)
		Unvaccinated	160 (97.6)	336 (95.5)	496 (96.1)	
		Total	164 (100.0)	352 (100.0)	516 (100.0)	
Symptom onset seasons [3]	2020/10-2021/3	Vaccinated	3 (0.7)	4 (2.0)	7 (1.1)	64.29% (-61.10%, 92.08%)
		Unvaccinated	412 (99.3)	196 (98.0)	608 (98.9)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (V260-080 analysis population) *(Continued)*

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
		Total	415 (100.0)	200 (100.0)	615 (100.0)	
	2021/10-2022/4	Vaccinated	5 (1.1)	49 (5.5)	54 (4.0)	80.42% (50.52%, 92.26%)
		Unvaccinated	441 (98.9)	846 (94.5)	1287 (96.0)	
		Total	446 (100.0)	895 (100.0)	1341 (100.0)	
	2022/10-2023/4	Vaccinated	4 (2.0)	42 (5.4)	46 (4.7)	64.57% (-0.00%, 87.44%)
		Unvaccinated	196 (98.0)	729 (94.6)	925 (95.3)	
		Total	200 (100.0)	771 (100.0)	971 (100.0)	
	2024/10-2025/4	Vaccinated	4 (0.9)	69 (8.5)	73 (5.8)	90.54% (73.90%, 96.57%)
		Unvaccinated	453 (99.1)	739 (91.5)	1192 (94.2)	
		Total	457 (100.0)	808 (100.0)	1265 (100.0)	
Gender	Male	Vaccinated	10 (1.1)	101 (6.2)	111 (4.3)	83.83% (68.88%, 91.60%)
		Unvaccinated	932 (98.9)	1522 (93.8)	2454 (95.7)	
		Total	942 (100.0)	1623 (100.0)	2565 (100.0)	
	Female	Vaccinated	6 (1.0)	63 (6.0)	69 (4.2)	83.49% (61.62%, 92.90%)
		Unvaccinated	570 (99.0)	988 (94.0)	1558 (95.8)	
		Total	576 (100.0)	1051 (100.0)	1627 (100.0)	
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	Vaccinated	15 (1.0)	163 (6.1)	178 (4.2)	84.62% (73.80%, 90.97%)
		Unvaccinated	1502 (99.0)	2510 (93.9)	4012 (95.8)	
		Total	1517 (100.0)	2673 (100.0)	4190 (100.0)	
	Both dose intervals > 10 weeks	Vaccinated	1 (0.1)	1 (0.04)	2 (0.05)	-67.11% (-2573.65%, 89.56%)

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.3.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases (V260-080 analysis population) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
	Unvaccinated	1502 (99.9)	2510 (100.0)	4012 (100.0)	
	Total	1503 (100.0)	2511 (100.0)	4014 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.3.3. Demographic and clinical characteristics of RVGE cases and control groups (V260-080 analysis population)

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
Age of onset (in months)	n (nmiss)	1518 (0)	2674 (0)	4192 (0)
	Mean (Std)	23.25 (14.497)	17.98 (12.537)	19.89 (13.518)
	Median	19.20	14.40	16.00
	Q1, Q3	13.70, 28.20	9.30, 22.40	10.70, 24.30
	Min, Max	3.8, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	265 (17.5)	1007 (37.7)	1272 (30.3)
	12-23 months	756 (49.8)	1079 (40.4)	1835 (43.8)
	24-35 months	251 (16.5)	331 (12.4)	582 (13.9)
	>=36 months	246 (16.2)	257 (9.6)	503 (12.0)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
Birth seasons (n, %) [1]	RV peak season	884 (58.2)	1529 (57.2)	2413 (57.6)
	Non-RV peak season	634 (41.8)	1145 (42.8)	1779 (42.4)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
Residence location (n, %)	Urban	917 (60.4)	1693 (63.3)	2610 (62.3)
	Rural	599 (39.5)	981 (36.7)	1580 (37.7)
	Missing	2 (0.1)	0	2 (0.05)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
Regions of study hospitals (n, %) [2]	East	622 (41.0)	1299 (48.6)	1921 (45.8)
	Central	378 (24.9)	680 (25.4)	1058 (25.2)
	West	518 (34.1)	695 (26.0)	1213 (28.9)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
Clinical settings (n, %)	Inpatient	1354 (89.2)	2322 (86.8)	3676 (87.7)
	Outpatient	164 (10.8)	352 (13.2)	516 (12.3)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)

The denominator is the number of patients in each group within V260-080 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 cases and control groups (V260-080 analysis population) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
Symptom onset seasons (n, %) [3]	2020/10-2021/3	415 (27.3)	200 (7.5)	615 (14.7)
	2021/10-2022/4	446 (29.4)	895 (33.5)	1341 (32.0)
	2022/10-2023/4	200 (13.2)	771 (28.8)	971 (23.2)
	2024/10-2025/4	457 (30.1)	808 (30.2)	1265 (30.2)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
Gender (n, %)	Male	942 (62.1)	1623 (60.7)	2565 (61.2)
	Female	576 (37.9)	1051 (39.3)	1627 (38.8)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
College and above for either parent's education level (n, %)	No	411 (27.1)	847 (31.7)	1258 (30.0)
	Yes	680 (44.8)	1608 (60.1)	2288 (54.6)
	Missing	427 (28.1)	219 (8.2)	646 (15.4)
	Total	1518 (100.0)	2674 (100.0)	4192 (100.0)
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	15 (93.8)	163 (99.4)	178 (98.9)
	Both dose intervals > 10 weeks	1 (6.3)	1 (0.6)	2 (1.1)
	Total	16 (100.0)	164 (100.0)	180 (100.0)

The denominator is the number of patients in each group within V260-080 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 (RVGE cases-V260-080 analysis population)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Age of onset (in months) (Continuous)	0.028	<0.001	1.029 (1.024, 1.034)
Birth seasons (RV peak season vs Non-RV peak season)	0.043	0.507	1.044 (0.919, 1.186)
Residence location (Urban vs Rural)	-0.120	0.070	0.887 (0.779, 1.010)
Regions of study hospitals (Central vs East)	0.149	0.064	1.161 (0.991, 1.360)
Regions of study hospitals (West vs East)	0.442	<0.001	1.557 (1.342, 1.806)
Clinical setting (Inpatient vs Outpatient)	0.224	0.026	1.252 (1.028, 1.524)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.300	<0.001	3.669 (2.992, 4.499)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.127	0.124	0.881 (0.750, 1.035)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.779	<0.001	0.459 (0.378, 0.556)
Gender (Male vs Female)	0.057	0.386	1.059 (0.930, 1.205)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.814	<0.001	0.163 (0.097, 0.273)

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

Table 14.3.5. Adjusted vaccine effectiveness against RVGE cases (V260-080 analysis population)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.041	<0.001	1.042 (1.036, 1.047)	
Residence location (Urban vs Rural) [1]	-0.146	0.049	0.865 (0.748, 0.999)	
Regions of study hospitals (Central vs East) [1]	0.295	<0.001	1.343 (1.129, 1.599)	
Regions of study hospitals (West vs East) [1]	0.601	<0.001	1.824 (1.543, 2.155)	
Clinical setting (Inpatient vs Outpatient) [1]	0.703	<0.001	2.019 (1.607, 2.537)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.722	<0.001	5.598 (4.464, 7.019)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	0.159	0.076	1.172 (0.983, 1.397)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-0.679	<0.001	0.507 (0.413, 0.622)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.778	<0.001	0.169 (0.099, 0.290)	83.10% (71.03%, 90.14%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Refer to the results of table 8.3.4, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 4190 (including 1516 cases and 2674 controls).

Table 14.4.1. Crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (V260-080 analysis population)

	Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Vaccinated	11 (1.2)	164 (6.1)	175 (4.8)	81.92% (66.55%, 90.22%)
Unvaccinated	931 (98.8)	2510 (93.9)	3441 (95.2)	
Total	942 (100.0)	2674 (100.0)	3616 (100.0)	

The denominator is the number of patients in each group within V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not received any rotavirus vaccines.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".

Table 14.4.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (V260-080 analysis population)

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Age of onset group	<=11 months	Vaccinated	3 (1.8)	46 (4.6)	49 (4.2)	62.46% (-22.09%, 88.45%)
		Unvaccinated	167 (98.2)	961 (95.4)	1128 (95.8)	
		Total	170 (100.0)	1007 (100.0)	1177 (100.0)	
	12-23 months	Vaccinated	5 (1.0)	77 (7.1)	82 (5.2)	86.42% (66.22%, 94.54%)
		Unvaccinated	479 (99.0)	1002 (92.9)	1481 (94.8)	
		Total	484 (100.0)	1079 (100.0)	1563 (100.0)	
	24-35 months	Vaccinated	0	27 (8.2)	27 (5.7)	NA*
		Unvaccinated	141 (100.0)	304 (91.8)	445 (94.3)	
		Total	141 (100.0)	331 (100.0)	472 (100.0)	
	>=36 months	Vaccinated	3 (2.0)	14 (5.4)	17 (4.2)	63.84% (-27.98%, 89.78%)
		Unvaccinated	144 (98.0)	243 (94.6)	387 (95.8)	
		Total	147 (100.0)	257 (100.0)	404 (100.0)	
Birth seasons	RV peak season [1]	Vaccinated	3 (0.5)	85 (5.6)	88 (4.2)	90.65% (70.30%, 97.06%)
		Unvaccinated	545 (99.5)	1444 (94.4)	1989 (95.8)	
		Total	548 (100.0)	1529 (100.0)	2077 (100.0)	
	Non-RV peak season	Vaccinated	8 (2.0)	79 (6.9)	87 (5.7)	72.01% (41.56%, 86.59%)
		Unvaccinated	386 (98.0)	1066 (93.1)	1452 (94.3)	
		Total	394 (100.0)	1145 (100.0)	1539 (100.0)	
Residence location	Urban	Vaccinated	11 (1.9)	116 (6.9)	127 (5.6)	73.06% (49.62%, 85.59%)
		Unvaccinated	555 (98.1)	1577 (93.1)	2132 (94.4)	
		Total	566 (100.0)	1693 (100.0)	2259 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.4.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (V260-080 analysis population) *(Continued)*

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
	Rural	Vaccinated	0	48 (4.9)	48 (3.5)	NA*
		Unvaccinated	374 (100.0)	933 (95.1)	1307 (96.5)	
		Total	374 (100.0)	981 (100.0)	1355 (100.0)	
Regions of study hospitals [2]	East	Vaccinated	2 (0.6)	71 (5.5)	73 (4.4)	90.28% (60.19%, 97.63%)
		Unvaccinated	356 (99.4)	1228 (94.5)	1584 (95.6)	
		Total	358 (100.0)	1299 (100.0)	1657 (100.0)	
	Central	Vaccinated	2 (1.0)	33 (4.9)	35 (4.0)	80.49% (17.99%, 95.36%)
		Unvaccinated	201 (99.0)	647 (95.1)	848 (96.0)	
		Total	203 (100.0)	680 (100.0)	883 (100.0)	
	West	Vaccinated	7 (1.8)	60 (8.6)	67 (6.2)	80.19% (56.22%, 91.04%)
		Unvaccinated	374 (98.2)	635 (91.4)	1009 (93.8)	
		Total	381 (100.0)	695 (100.0)	1076 (100.0)	
Clinical setting	Inpatient	Vaccinated	9 (1.1)	148 (6.4)	157 (5.0)	83.86% (68.21%, 91.80%)
		Unvaccinated	819 (98.9)	2174 (93.6)	2993 (95.0)	
		Total	828 (100.0)	2322 (100.0)	3150 (100.0)	
	Outpatient	Vaccinated	2 (1.8)	16 (4.5)	18 (3.9)	62.50% (-65.64%, 91.51%)
		Unvaccinated	112 (98.2)	336 (95.5)	448 (96.1)	
		Total	114 (100.0)	352 (100.0)	466 (100.0)	
Symptom onset seasons [3]	2020/10-2021/3	Vaccinated	3 (0.8)	4 (2.0)	7 (1.2)	60.04% (-80.33%, 91.15%)
		Unvaccinated	368 (99.2)	196 (98.0)	564 (98.8)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.4.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (V260-080 analysis population) *(Continued)*

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
		Total	371 (100.0)	200 (100.0)	571 (100.0)	
	2021/10-2022/4	Vaccinated	3 (2.4)	49 (5.5)	52 (5.1)	58.22% (-36.07%, 87.17%)
		Unvaccinated	124 (97.6)	846 (94.5)	970 (94.9)	
		Total	127 (100.0)	895 (100.0)	1022 (100.0)	
	2022/10-2023/4	Vaccinated	3 (3.0)	42 (5.4)	45 (5.2)	46.32% (-76.51%, 83.67%)
		Unvaccinated	97 (97.0)	729 (94.6)	826 (94.8)	
		Total	100 (100.0)	771 (100.0)	871 (100.0)	
	2024/10-2025/4	Vaccinated	2 (0.6)	69 (8.5)	71 (6.2)	93.74% (74.30%, 98.47%)
		Unvaccinated	342 (99.4)	739 (91.5)	1081 (93.8)	
		Total	344 (100.0)	808 (100.0)	1152 (100.0)	
Gender	Male	Vaccinated	7 (1.2)	101 (6.2)	108 (4.9)	81.78% (60.57%, 91.58%)
		Unvaccinated	579 (98.8)	1522 (93.8)	2101 (95.1)	
		Total	586 (100.0)	1623 (100.0)	2209 (100.0)	
	Female	Vaccinated	4 (1.1)	63 (6.0)	67 (4.8)	82.18% (50.68%, 93.56%)
		Unvaccinated	352 (98.9)	988 (94.0)	1340 (95.2)	
		Total	356 (100.0)	1051 (100.0)	1407 (100.0)	
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	Vaccinated	10 (1.1)	163 (6.1)	173 (4.8)	83.46% (68.54%, 91.30%)
		Unvaccinated	931 (98.9)	2510 (93.9)	3441 (95.2)	
		Total	941 (100.0)	2673 (100.0)	3614 (100.0)	
	Both dose intervals > 10 weeks	Vaccinated	1 (0.1)	1 (0.04)	2 (0.1)	-169.38% (-4211.11%, 83.17%)

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.4.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (V260-080 analysis population) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
	Unvaccinated	931 (99.9)	2510 (100.0)	3441 (99.9)	
	Total	932 (100.0)	2511 (100.0)	3443 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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 group.

Table 14.4.3. Demographic and clinical characteristics of RVGE cases due to G1/G2/G3/G4/G9 types and control groups (V260-080 analysis population)

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
Age of onset (in months)	n (nmiss)	942 (0)	2674 (0)	3616 (0)
	Mean (Std)	22.92 (14.523)	17.98 (12.537)	19.27 (13.260)
	Median	18.85	14.40	15.40
	Q1, Q3	13.50, 26.60	9.30, 22.40	10.30, 23.50
	Min, Max	4.1, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	170 (18.0)	1007 (37.7)	1177 (32.5)
	12-23 months	484 (51.4)	1079 (40.4)	1563 (43.2)
	24-35 months	141 (15.0)	331 (12.4)	472 (13.1)
	>=36 months	147 (15.6)	257 (9.6)	404 (11.2)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
Birth seasons (n, %) [1]	RV peak season	548 (58.2)	1529 (57.2)	2077 (57.4)
	Non-RV peak season	394 (41.8)	1145 (42.8)	1539 (42.6)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
Residence location (n, %)	Urban	566 (60.1)	1693 (63.3)	2259 (62.5)
	Rural	374 (39.7)	981 (36.7)	1355 (37.5)
	Missing	2 (0.2)	0	2 (0.1)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
Regions of study hospitals (n, %) [2]	East	358 (38.0)	1299 (48.6)	1657 (45.8)
	Central	203 (21.5)	680 (25.4)	883 (24.4)
	West	381 (40.4)	695 (26.0)	1076 (29.8)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
Clinical settings (n, %)	Inpatient	828 (87.9)	2322 (86.8)	3150 (87.1)
	Outpatient	114 (12.1)	352 (13.2)	466 (12.9)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)

The denominator is the number of patients in each group within V260-080 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. Demographic and clinical characteristics of RVGE cases due to G1/G2/G3/G4/G9 types and control groups (V260-080 analysis population) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
Symptom onset seasons (n, %) [3]	2020/10-2021/3	371 (39.4)	200 (7.5)	571 (15.8)
	2021/10-2022/4	127 (13.5)	895 (33.5)	1022 (28.3)
	2022/10-2023/4	100 (10.6)	771 (28.8)	871 (24.1)
	2024/10-2025/4	344 (36.5)	808 (30.2)	1152 (31.9)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
Gender (n, %)	Male	586 (62.2)	1623 (60.7)	2209 (61.1)
	Female	356 (37.8)	1051 (39.3)	1407 (38.9)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
College and above for either parent's education level (n, %)	No	196 (20.8)	847 (31.7)	1043 (28.8)
	Yes	371 (39.4)	1608 (60.1)	1979 (54.7)
	Missing	375 (39.8)	219 (8.2)	594 (16.4)
	Total	942 (100.0)	2674 (100.0)	3616 (100.0)
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	10 (90.9)	163 (99.4)	173 (98.9)
	Both dose intervals > 10 weeks	1 (9.1)	1 (0.6)	2 (1.1)
	Total	11 (100.0)	164 (100.0)	175 (100.0)

The denominator is the number of patients in each group within V260-080 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. Univariate Logistic Regression (G1/G2/G3/G4/G9-V260-080 analysis population)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Age of onset (in months) (Continuous)	0.026	<0.001	1.026 (1.021, 1.032)
Birth seasons (RV peak season vs Non-RV peak season)	0.041	0.596	1.041 (0.896, 1.211)
Residence location (Urban vs Rural)	-0.131	0.091	0.877 (0.753, 1.021)
Regions of study hospitals (Central vs East)	0.080	0.423	1.083 (0.891, 1.317)
Regions of study hospitals (West vs East)	0.688	<0.001	1.990 (1.677, 2.361)
Clinical setting (Inpatient vs Outpatient)	0.096	0.403	1.101 (0.879, 1.380)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.472	<0.001	4.357 (3.520, 5.392)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-1.099	<0.001	0.333 (0.266, 0.417)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-1.188	<0.001	0.305 (0.239, 0.389)
Gender (Male vs Female)	0.064	0.413	1.066 (0.915, 1.242)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.710	<0.001	0.181 (0.098, 0.335)

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

Table 14.4.5. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (V260-080 analysis population)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.036	<0.001	1.037 (1.031, 1.043)	
Residence location (Urban vs Rural) [1]	-0.195	0.032	0.823 (0.689, 0.983)	
Regions of study hospitals (Central vs East) [1]	0.233	0.040	1.262 (1.010, 1.576)	
Regions of study hospitals (West vs East) [1]	0.818	<0.001	2.267 (1.855, 2.770)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.679	<0.001	5.359 (4.251, 6.756)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	-0.874	<0.001	0.417 (0.329, 0.529)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-1.182	<0.001	0.307 (0.238, 0.396)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.700	<0.001	0.183 (0.095, 0.351)	81.73% (64.93%, 90.48%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Refer to the results of table 8.4.4, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 3614 (including 940 cases and 2674 controls).

Table 14.5.1. Crude vaccine effectiveness against RVGE cases (Sensitivity analysis 1)

	Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Vaccinated	16 (1.0)	164 (5.9)	180 (4.2)	83.36% (72.09%, 90.08%)
Unvaccinated	1529 (99.0)	2608 (94.1)	4137 (95.8)	
Total	1545 (100.0)	2772 (100.0)	4317 (100.0)	

The denominator is the number of patients in each group within V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not received any rotavirus vaccines.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
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	3 (1.1)	46 (4.4)	49 (3.7)	75.67% (21.17%, 92.49%)
		Unvaccinated	267 (98.9)	996 (95.6)	1263 (96.3)	
		Total	270 (100.0)	1042 (100.0)	1312 (100.0)	
	12-23 months	Vaccinated	10 (1.3)	77 (6.9)	87 (4.6)	82.21% (65.39%, 90.85%)
		Unvaccinated	762 (98.7)	1044 (93.1)	1806 (95.4)	
		Total	772 (100.0)	1121 (100.0)	1893 (100.0)	
	24-35 months	Vaccinated	0	27 (7.9)	27 (4.5)	NA*
		Unvaccinated	256 (100.0)	316 (92.1)	572 (95.5)	
		Total	256 (100.0)	343 (100.0)	599 (100.0)	
	>=36 months	Vaccinated	3 (1.2)	14 (5.3)	17 (3.3)	77.87% (22.03%, 93.72%)
		Unvaccinated	244 (98.8)	252 (94.7)	496 (96.7)	
		Total	247 (100.0)	266 (100.0)	513 (100.0)	
Birth seasons	RV peak season [1]	Vaccinated	5 (0.6)	85 (5.4)	90 (3.6)	90.14% (75.62%, 96.01%)
		Unvaccinated	890 (99.4)	1491 (94.6)	2381 (96.4)	
		Total	895 (100.0)	1576 (100.0)	2471 (100.0)	
	Non-RV peak season	Vaccinated	11 (1.7)	79 (6.6)	90 (4.9)	75.65% (53.90%, 87.13%)
		Unvaccinated	639 (98.3)	1117 (93.4)	1756 (95.1)	
		Total	650 (100.0)	1196 (100.0)	1846 (100.0)	
Residence location	Urban	Vaccinated	15 (1.6)	116 (6.6)	131 (4.9)	76.87% (60.17%, 86.57%)
		Unvaccinated	920 (98.4)	1644 (93.4)	2564 (95.1)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

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)*
		Total	935 (100.0)	1760 (100.0)	2695 (100.0)	
	Rural	Vaccinated	1 (0.2)	48 (4.7)	49 (3.0)	96.69% (75.95%, 99.54%)
		Unvaccinated	606 (99.8)	963 (95.3)	1569 (97.0)	
		Total	607 (100.0)	1011 (100.0)	1618 (100.0)	
Regions of study hospitals [2]	East	Vaccinated	3 (0.5)	71 (5.3)	74 (3.8)	91.43% (72.72%, 97.31%)
		Unvaccinated	622 (99.5)	1259 (94.7)	1881 (96.2)	
		Total	625 (100.0)	1330 (100.0)	1955 (100.0)	
	Central	Vaccinated	3 (0.8)	33 (4.6)	36 (3.3)	83.93% (47.27%, 95.10%)
		Unvaccinated	387 (99.2)	684 (95.4)	1071 (96.7)	
		Total	390 (100.0)	717 (100.0)	1107 (100.0)	
	West	Vaccinated	10 (1.9)	60 (8.3)	70 (5.6)	78.68% (57.95%, 89.19%)
		Unvaccinated	520 (98.1)	665 (91.7)	1185 (94.4)	
		Total	530 (100.0)	725 (100.0)	1255 (100.0)	
Clinical setting	Inpatient	Vaccinated	12 (0.9)	148 (6.2)	160 (4.2)	86.62% (75.82%, 92.60%)
		Unvaccinated	1365 (99.1)	2252 (93.8)	3617 (95.8)	
		Total	1377 (100.0)	2400 (100.0)	3777 (100.0)	
	Outpatient	Vaccinated	4 (2.4)	16 (4.3)	20 (3.7)	45.73% (-64.86%, 82.14%)
		Unvaccinated	164 (97.6)	356 (95.7)	520 (96.3)	
		Total	168 (100.0)	372 (100.0)	540 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

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)*
Symptom onset seasons [3]	2020/10-2021/3	Vaccinated	3 (0.7)	4 (2.0)	7 (1.1)	64.01% (-62.33%, 92.02%)
		Unvaccinated	413 (99.3)	198 (98.0)	611 (98.9)	
		Total	416 (100.0)	202 (100.0)	618 (100.0)	
	2021/10-2022/4	Vaccinated	5 (1.1)	49 (5.1)	54 (3.8)	79.88% (49.16%, 92.04%)
		Unvaccinated	463 (98.9)	913 (94.9)	1376 (96.2)	
		Total	468 (100.0)	962 (100.0)	1430 (100.0)	
	2022/10-2023/4	Vaccinated	4 (2.0)	42 (5.3)	46 (4.6)	63.91% (-1.82%, 87.21%)
		Unvaccinated	198 (98.0)	750 (94.7)	948 (95.4)	
		Total	202 (100.0)	792 (100.0)	994 (100.0)	
	2024/10-2025/4	Vaccinated	4 (0.9)	69 (8.5)	73 (5.7)	90.48% (73.74%, 96.55%)
		Unvaccinated	455 (99.1)	747 (91.5)	1202 (94.3)	
		Total	459 (100.0)	816 (100.0)	1275 (100.0)	
Gender	Male	Vaccinated	10 (1.0)	101 (6.0)	111 (4.2)	83.46% (68.17%, 91.41%)
		Unvaccinated	949 (99.0)	1585 (94.0)	2534 (95.8)	
		Total	959 (100.0)	1686 (100.0)	2645 (100.0)	
	Female	Vaccinated	6 (1.0)	63 (5.8)	69 (4.1)	83.20% (60.95%, 92.77%)
		Unvaccinated	580 (99.0)	1023 (94.2)	1603 (95.9)	
		Total	586 (100.0)	1086 (100.0)	1672 (100.0)	
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	Vaccinated	15 (1.0)	163 (5.9)	178 (4.1)	84.30% (73.26%, 90.78%)
		Unvaccinated	1529 (99.0)	2608 (94.1)	4137 (95.9)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

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)*
	Total	1544 (100.0)	2771 (100.0)	4315 (100.0)	
Both dose intervals > 10 weeks	Vaccinated	1 (0.1)	1 (0.04)	2 (0.05)	-70.57% (-2628.93%, 89.34%)
	Unvaccinated	1529 (99.9)	2608 (100.0)	4137 (100.0)	
	Total	1530 (100.0)	2609 (100.0)	4139 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

Table 14.5.3. Demographic and clinical characteristics of RVGE cases (Sensitivity analysis 1)

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
Age of onset (in months)	n (nmiss)	1545 (0)	2772 (0)	4317 (0)
	Mean (Std)	23.18 (14.438)	17.96 (12.468)	19.83 (13.441)
	Median	19.20	14.40	16.00
	Q1, Q3	13.70, 28.10	9.30, 22.40	10.70, 24.30
	Min, Max	3.8, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	270 (17.5)	1042 (37.6)	1312 (30.4)
	12-23 months	772 (50.0)	1121 (40.4)	1893 (43.8)
	24-35 months	256 (16.6)	343 (12.4)	599 (13.9)
	>=36 months	247 (16.0)	266 (9.6)	513 (11.9)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Birth seasons (n, %) [1]	RV peak season	895 (57.9)	1576 (56.9)	2471 (57.2)
	Non-RV peak season	650 (42.1)	1196 (43.1)	1846 (42.8)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Residence location (n, %)	Urban	935 (60.5)	1760 (63.5)	2695 (62.4)
	Rural	607 (39.3)	1011 (36.5)	1618 (37.5)
	Missing	3 (0.2)	1 (0.04)	4 (0.1)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Regions of study hospitals (n, %) [2]	East	625 (40.5)	1330 (48.0)	1955 (45.3)
	Central	390 (25.2)	717 (25.9)	1107 (25.6)
	West	530 (34.3)	725 (26.2)	1255 (29.1)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Clinical settings (n, %)	Inpatient	1377 (89.1)	2400 (86.6)	3777 (87.5)
	Outpatient	168 (10.9)	372 (13.4)	540 (12.5)

The denominator is the number of patients in each group within V260-080 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 cases (Sensitivity analysis 1) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	416 (26.9)	202 (7.3)	618 (14.3)
	2021/10-2022/4	468 (30.3)	962 (34.7)	1430 (33.1)
	2022/10-2023/4	202 (13.1)	792 (28.6)	994 (23.0)
	2024/10-2025/4	459 (29.7)	816 (29.4)	1275 (29.5)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Gender (n, %)	Male	959 (62.1)	1686 (60.8)	2645 (61.3)
	Female	586 (37.9)	1086 (39.2)	1672 (38.7)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
College and above for either parent's education level (n, %)	No	418 (27.1)	880 (31.7)	1298 (30.1)
	Yes	696 (45.0)	1668 (60.2)	2364 (54.8)
	Missing	431 (27.9)	224 (8.1)	655 (15.2)
	Total	1545 (100.0)	2772 (100.0)	4317 (100.0)
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	15 (93.8)	163 (99.4)	178 (98.9)
	Both dose intervals > 10 weeks	1 (6.3)	1 (0.6)	2 (1.1)
	Total	16 (100.0)	164 (100.0)	180 (100.0)

The denominator is the number of patients in each group within V260-080 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 (RVGE cases-Sensitivity analysis 1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Age of onset (in months) (Continuous)	0.028	<0.001	1.029 (1.024, 1.034)
Birth seasons (RV peak season vs Non-RV peak season)	0.044	0.494	1.045 (0.921, 1.185)
Residence location (Urban vs Rural)	-0.122	0.061	0.885 (0.778, 1.006)
Regions of study hospitals (Central vs East)	0.146	0.066	1.157 (0.991, 1.352)
Regions of study hospitals (West vs East)	0.442	<0.001	1.556 (1.343, 1.802)
Clinical setting (Inpatient vs Outpatient)	0.239	0.016	1.270 (1.047, 1.542)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.298	<0.001	3.661 (2.988, 4.487)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.145	0.073	0.865 (0.738, 1.014)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.791	<0.001	0.453 (0.374, 0.550)
Gender (Male vs Female)	0.053	0.420	1.054 (0.927, 1.198)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.793	<0.001	0.166 (0.099, 0.279)

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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.041	<0.001	1.042 (1.036, 1.047)	
Residence location (Urban vs Rural) [1]	-0.155	0.035	0.857 (0.742, 0.989)	
Regions of study hospitals (Central vs East) [1]	0.300	<0.001	1.350 (1.137, 1.602)	
Regions of study hospitals (West vs East) [1]	0.606	<0.001	1.832 (1.553, 2.161)	
Clinical setting (Inpatient vs Outpatient) [1]	0.701	<0.001	2.016 (1.612, 2.523)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.718	<0.001	5.572 (4.448, 6.980)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	0.134	0.130	1.143 (0.961, 1.359)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-0.700	<0.001	0.496 (0.405, 0.608)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.762	<0.001	0.172 (0.100, 0.294)	82.83% (70.56%, 89.98%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.4, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 4313 (including 1542 cases and 2771 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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.041	<0.001	1.042 (1.036, 1.047)	
Residence location (Urban vs Rural) [2]	-0.146	0.049	0.865 (0.748, 0.999)	
Regions of study hospitals (Central vs East) [2]	0.295	<0.001	1.343 (1.129, 1.599)	
Regions of study hospitals (West vs East) [2]	0.601	<0.001	1.824 (1.543, 2.155)	
Clinical setting (Inpatient vs Outpatient) [2]	0.703	<0.001	2.019 (1.607, 2.537)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.722	<0.001	5.598 (4.464, 7.019)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	0.159	0.076	1.172 (0.983, 1.397)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-0.679	<0.001	0.507 (0.413, 0.622)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [1]	-1.778	<0.001	0.169 (0.099, 0.290)	83.10% (71.03%, 90.14%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Age of onset (in months), symptom onset seasons, received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 are the fixed variables in the logistic regression.
[2] Refer to the results of table 8.3.4, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 4190 (including 1516 cases and 2674 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 >= 0.1.

Table 14.5.7.1. Conditional Univariate Logistic Regression (RVGE cases-Sensitivity analysis 3-1:1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.132	0.141	0.876 (0.735, 1.045)
Residence location (Urban vs Rural)	-0.023	0.792	0.977 (0.823, 1.160)
Regions of study hospitals (Central vs East)	0.193	0.069	1.212 (0.985, 1.492)
Regions of study hospitals (West vs East)	0.326	0.002	1.385 (1.130, 1.698)
Clinical setting (Inpatient vs Outpatient)	0.599	<0.001	1.821 (1.352, 2.453)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-2.015	<0.001	0.133 (0.073, 0.244)

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 seasons).
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 (RVGE cases-Sensitivity analysis 3-1:2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.057	0.472	0.945 (0.810, 1.102)
Residence location (Urban vs Rural)	0.010	0.896	1.010 (0.866, 1.179)
Regions of study hospitals (Central vs East)	0.324	<0.001	1.383 (1.144, 1.672)
Regions of study hospitals (West vs East)	0.398	<0.001	1.489 (1.241, 1.787)
Clinical setting (Inpatient vs Outpatient)	0.541	<0.001	1.719 (1.313, 2.249)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.812	<0.001	0.163 (0.090, 0.296)

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 seasons).
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 (RVGE cases-Sensitivity analysis 3-1:3)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.051	0.512	0.951 (0.817, 1.106)
Residence location (Urban vs Rural)	0.003	0.964	1.004 (0.862, 1.168)
Regions of study hospitals (Central vs East)	0.316	<0.001	1.372 (1.141, 1.650)
Regions of study hospitals (West vs East)	0.391	<0.001	1.479 (1.237, 1.769)
Clinical setting (Inpatient vs Outpatient)	0.509	<0.001	1.663 (1.275, 2.170)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.796	<0.001	0.166 (0.092, 0.300)

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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Regions of study hospitals (Central vs East) [1]	0.147	0.181	1.158 (0.934, 1.435)	
Regions of study hospitals (West vs East) [1]	0.452	<0.001	1.572 (1.270, 1.945)	
Clinical setting (Inpatient vs Outpatient) [1]	0.654	<0.001	1.924 (1.413, 2.620)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-2.095	<0.001	0.123 (0.067, 0.226)	87.69% (77.39%, 93.30%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.7.1, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 2140 (including 1070 cases and 1070 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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Regions of study hospitals (Central vs East) [1]	0.278	0.005	1.321 (1.090, 1.601)	
Regions of study hospitals (West vs East) [1]	0.480	<0.001	1.616 (1.341, 1.946)	
Clinical setting (Inpatient vs Outpatient) [1]	0.582	<0.001	1.790 (1.360, 2.356)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.878	<0.001	0.153 (0.084, 0.279)	84.71% (72.15%, 91.61%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.7.2, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 2957 (including 1070 cases and 1887 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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Regions of study hospitals (Central vs East) [1]	0.288	0.003	1.334 (1.106, 1.609)	
Regions of study hospitals (West vs East) [1]	0.462	<0.001	1.588 (1.324, 1.904)	
Clinical setting (Inpatient vs Outpatient) [1]	0.544	<0.001	1.722 (1.314, 2.257)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.865	<0.001	0.155 (0.085, 0.282)	84.51% (71.85%, 91.47%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.7.3, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 3262 (including 1070 cases and 2192 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 seasons).
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 (RVGE cases-Sensitivity analysis 4-1:1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	0.067	0.380	1.069 (0.921, 1.242)
Residence location (Urban vs Rural)	-0.193	0.010	0.825 (0.713, 0.954)
Regions of study hospitals (Central vs East)	0.250	0.007	1.284 (1.070, 1.540)
Regions of study hospitals (West vs East)	0.452	<0.001	1.572 (1.322, 1.870)
Clinical setting (Inpatient vs Outpatient)	0.420	<0.001	1.522 (1.226, 1.890)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.727	<0.001	0.178 (0.104, 0.303)

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 seasons).
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 (RVGE cases-Sensitivity analysis 4-1:2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	0.039	0.587	1.039 (0.904, 1.194)
Residence location (Urban vs Rural)	-0.181	0.009	0.834 (0.728, 0.956)
Regions of study hospitals (Central vs East)	0.265	0.002	1.304 (1.102, 1.543)
Regions of study hospitals (West vs East)	0.464	<0.001	1.590 (1.354, 1.867)
Clinical setting (Inpatient vs Outpatient)	0.426	<0.001	1.531 (1.250, 1.876)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.747	<0.001	0.174 (0.103, 0.294)

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 seasons).
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 (RVGE cases-Sensitivity analysis 4-1:3)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.000	>.999	1.000 (0.873, 1.146)
Residence location (Urban vs Rural)	-0.162	0.018	0.850 (0.744, 0.972)
Regions of study hospitals (Central vs East)	0.253	0.003	1.287 (1.091, 1.519)
Regions of study hospitals (West vs East)	0.459	<0.001	1.583 (1.352, 1.853)
Clinical setting (Inpatient vs Outpatient)	0.400	<0.001	1.493 (1.219, 1.827)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.750	<0.001	0.174 (0.103, 0.292)

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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Residence location (Urban vs Rural) [1]	-0.195	0.012	0.822 (0.706, 0.959)	
Regions of study hospitals (Central vs East) [1]	0.213	0.025	1.237 (1.027, 1.491)	
Regions of study hospitals (West vs East) [1]	0.574	<0.001	1.776 (1.479, 2.132)	
Clinical setting (Inpatient vs Outpatient) [1]	0.494	<0.001	1.638 (1.301, 2.063)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.748	<0.001	0.174 (0.102, 0.298)	82.59% (70.16%, 89.85%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.9.1, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 3028 (including 1514 cases and 1514 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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Residence location (Urban vs Rural) [1]	-0.191	0.008	0.826 (0.717, 0.952)	
Regions of study hospitals (Central vs East) [1]	0.226	0.010	1.254 (1.056, 1.489)	
Regions of study hospitals (West vs East) [1]	0.575	<0.001	1.777 (1.503, 2.101)	
Clinical setting (Inpatient vs Outpatient) [1]	0.513	<0.001	1.670 (1.348, 2.069)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.784	<0.001	0.168 (0.099, 0.285)	83.20% (71.49%, 90.10%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.9.2, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 3750 (including 1514 cases and 2236 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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Residence location (Urban vs Rural) [1]	-0.168	0.018	0.845 (0.735, 0.972)	
Regions of study hospitals (Central vs East) [1]	0.216	0.012	1.241 (1.048, 1.468)	
Regions of study hospitals (West vs East) [1]	0.557	<0.001	1.746 (1.482, 2.056)	
Clinical setting (Inpatient vs Outpatient) [1]	0.477	<0.001	1.612 (1.303, 1.994)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.768	<0.001	0.171 (0.101, 0.289)	82.94% (71.13%, 89.91%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.9.3, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 4091 (including 1514 cases and 2577 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 seasons).
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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Age of onset (in months) (Continuous)	0.035	<0.001	1.036 (1.031, 1.041)
Birth seasons (RV peak season vs Non-RV peak season)	0.017	0.814	1.017 (0.881, 1.175)
Residence location (Urban vs Rural)	-0.036	0.636	0.965 (0.833, 1.118)
Regions of study hospitals (Central vs East)	0.127	0.158	1.135 (0.952, 1.353)
Regions of study hospitals (West vs East)	0.282	0.001	1.326 (1.119, 1.573)
Clinical setting (Inpatient vs Outpatient)	0.447	<0.001	1.563 (1.210, 2.019)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-0.126	0.128	0.882 (0.750, 1.037)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-0.784	<0.001	0.457 (0.376, 0.555)
Gender (Male vs Female)	0.108	0.151	1.114 (0.961, 1.291)
College and above for either parent's education level (Yes vs No)	-0.138	0.069	0.871 (0.752, 1.011)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.836	<0.001	0.160 (0.088, 0.288)

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)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.040	<0.001	1.040 (1.035, 1.046)	
Regions of study hospitals (Central vs East) [1]	0.297	0.002	1.346 (1.116, 1.624)	
Regions of study hospitals (West vs East) [1]	0.528	<0.001	1.696 (1.413, 2.036)	
Clinical setting (Inpatient vs Outpatient) [1]	0.604	<0.001	1.830 (1.393, 2.404)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	0.120	0.183	1.128 (0.945, 1.346)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-0.683	<0.001	0.505 (0.412, 0.620)	
College and above for either parent's education level (Yes vs No) [1]	-0.147	0.069	0.863 (0.736, 1.011)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.946	<0.001	0.143 (0.078, 0.263)	85.72% (73.75%, 92.23%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Refer to the results of table 8.5.11, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 3546 (including 1091 cases and 2455 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. Crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1)

	Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Vaccinated	11 (1.2)	164 (5.9)	175 (4.7)	81.43% (65.65%, 89.96%)
Unvaccinated	942 (98.8)	2608 (94.1)	3550 (95.3)	
Total	953 (100.0)	2772 (100.0)	3725 (100.0)	

The denominator is the number of patients in each group within V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not received any rotavirus vaccines.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.6.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1)

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Age of onset group	<=11 months	Vaccinated	3 (1.7)	46 (4.4)	49 (4.0)	62.00% (-23.54%, 88.31%)
		Unvaccinated	171 (98.3)	996 (95.6)	1167 (96.0)	
		Total	174 (100.0)	1042 (100.0)	1216 (100.0)	
	12-23 months	Vaccinated	5 (1.0)	77 (6.9)	82 (5.1)	85.93% (65.02%, 94.34%)
		Unvaccinated	482 (99.0)	1044 (93.1)	1526 (94.9)	
		Total	487 (100.0)	1121 (100.0)	1608 (100.0)	
	24-35 months	Vaccinated	0	27 (7.9)	27 (5.5)	NA*
		Unvaccinated	144 (100.0)	316 (92.1)	460 (94.5)	
		Total	144 (100.0)	343 (100.0)	487 (100.0)	
	>=36 months	Vaccinated	3 (2.0)	14 (5.3)	17 (4.1)	62.76% (-31.76%, 89.47%)
		Unvaccinated	145 (98.0)	252 (94.7)	397 (95.9)	
		Total	148 (100.0)	266 (100.0)	414 (100.0)	
Birth seasons	RV peak season [1]	Vaccinated	3 (0.5)	85 (5.4)	88 (4.1)	90.36% (69.42%, 96.96%)
		Unvaccinated	547 (99.5)	1491 (94.6)	2038 (95.9)	
		Total	550 (100.0)	1576 (100.0)	2126 (100.0)	
	Non-RV peak season	Vaccinated	8 (2.0)	79 (6.6)	87 (5.4)	71.34% (40.18%, 86.27%)
		Unvaccinated	395 (98.0)	1117 (93.4)	1512 (94.6)	
		Total	403 (100.0)	1196 (100.0)	1599 (100.0)	
Residence location	Urban	Vaccinated	11 (1.9)	116 (6.6)	127 (5.4)	72.18% (48.01%, 85.12%)
		Unvaccinated	561 (98.1)	1644 (93.4)	2205 (94.6)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

Table 14.6.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1) *(Continued)*

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
		Total	572 (100.0)	1760 (100.0)	2332 (100.0)	
	Rural	Vaccinated	0	48 (4.7)	48 (3.5)	NA*
		Unvaccinated	378 (100.0)	963 (95.3)	1341 (96.5)	
		Total	378 (100.0)	1011 (100.0)	1389 (100.0)	
Regions of study hospitals [2]	East	Vaccinated	2 (0.6)	71 (5.3)	73 (4.3)	90.09% (59.42%, 97.58%)
		Unvaccinated	358 (99.4)	1259 (94.7)	1617 (95.7)	
		Total	360 (100.0)	1330 (100.0)	1690 (100.0)	
	Central	Vaccinated	2 (1.0)	33 (4.6)	35 (3.8)	79.88% (15.42%, 95.21%)
		Unvaccinated	206 (99.0)	684 (95.4)	890 (96.2)	
		Total	208 (100.0)	717 (100.0)	925 (100.0)	
	West	Vaccinated	7 (1.8)	60 (8.3)	67 (6.0)	79.48% (54.64%, 90.71%)
		Unvaccinated	378 (98.2)	665 (91.7)	1043 (94.0)	
		Total	385 (100.0)	725 (100.0)	1110 (100.0)	
Clinical setting	Inpatient	Vaccinated	9 (1.1)	148 (6.2)	157 (4.9)	83.46% (67.43%, 91.60%)
		Unvaccinated	828 (98.9)	2252 (93.8)	3080 (95.1)	
		Total	837 (100.0)	2400 (100.0)	3237 (100.0)	
	Outpatient	Vaccinated	2 (1.7)	16 (4.3)	18 (3.7)	60.96% (-72.35%, 91.16%)
		Unvaccinated	114 (98.3)	356 (95.7)	470 (96.3)	
		Total	116 (100.0)	372 (100.0)	488 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

Table 14.6.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1) *(Continued)*

			Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
Symptom onset seasons [3]	2020/10-2021/3	Vaccinated	3 (0.8)	4 (2.0)	7 (1.2)	59.74% (-81.66%, 91.08%)
		Unvaccinated	369 (99.2)	198 (98.0)	567 (98.8)	
		Total	372 (100.0)	202 (100.0)	574 (100.0)	
	2021/10-2022/4	Vaccinated	3 (2.3)	49 (5.1)	52 (4.7)	56.99% (-39.96%, 86.79%)
		Unvaccinated	130 (97.7)	913 (94.9)	1043 (95.3)	
		Total	133 (100.0)	962 (100.0)	1095 (100.0)	
	2022/10-2023/4	Vaccinated	3 (2.9)	42 (5.3)	45 (5.0)	45.89% (-77.86%, 83.54%)
		Unvaccinated	99 (97.1)	750 (94.7)	849 (95.0)	
		Total	102 (100.0)	792 (100.0)	894 (100.0)	
	2024/10-2025/4	Vaccinated	2 (0.6)	69 (8.5)	71 (6.1)	93.71% (74.18%, 98.47%)
		Unvaccinated	344 (99.4)	747 (91.5)	1091 (93.9)	
		Total	346 (100.0)	816 (100.0)	1162 (100.0)	
Gender	Male	Vaccinated	7 (1.2)	101 (6.0)	108 (4.7)	81.25% (59.44%, 91.34%)
		Unvaccinated	586 (98.8)	1585 (94.0)	2171 (95.3)	
		Total	593 (100.0)	1686 (100.0)	2279 (100.0)	
	Female	Vaccinated	4 (1.1)	63 (5.8)	67 (4.6)	81.75% (49.51%, 93.41%)
		Unvaccinated	356 (98.9)	1023 (94.2)	1379 (95.4)	
		Total	360 (100.0)	1086 (100.0)	1446 (100.0)	
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	Vaccinated	10 (1.1)	163 (5.9)	173 (4.6)	83.01% (67.69%, 91.07%)
		Unvaccinated	942 (98.9)	2608 (94.1)	3550 (95.4)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

Table 14.6.2. Subgroup analysis of crude vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*	*VE (%, 95% CI)*
	Total	952 (100.0)	2771 (100.0)	3723 (100.0)	
Both dose intervals > 10 weeks	Vaccinated	1 (0.1)	1 (0.04)	2 (0.1)	-176.57% (-4326.02%, 82.72%)
	Unvaccinated	942 (99.9)	2608 (100.0)	3550 (99.9)	
	Total	943 (100.0)	2609 (100.0)	3552 (100.0)	

The denominator is the number of patients in each subgroup within each group of V260-080 analysis population.
Vaccinated denotes children fully vaccinated with 3 doses of ROTATEQ with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3.
Unvaccinated denotes children who have not 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.
* NA=Not Applicable: No patient with ELISA positive results in the vaccinated group.

Table 14.6.3. Demographic and clinical characteristics of RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1)

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
Age of onset (in months)	n (nmiss)	953 (0)	2772 (0)	3725 (0)
	Mean (Std)	22.90 (14.512)	17.96 (12.468)	19.22 (13.197)
	Median	18.90	14.40	15.40
	Q1, Q3	13.50, 26.60	9.30, 22.40	10.20, 23.50
	Min, Max	4.1, 78.0	3.7, 77.4	3.7, 78.0
	<=11 months	174 (18.3)	1042 (37.6)	1216 (32.6)
	12-23 months	487 (51.1)	1121 (40.4)	1608 (43.2)
	24-35 months	144 (15.1)	343 (12.4)	487 (13.1)
	>=36 months	148 (15.5)	266 (9.6)	414 (11.1)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Birth seasons (n, %) [1]	RV peak season	550 (57.7)	1576 (56.9)	2126 (57.1)
	Non-RV peak season	403 (42.3)	1196 (43.1)	1599 (42.9)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Residence location (n, %)	Urban	572 (60.0)	1760 (63.5)	2332 (62.6)
	Rural	378 (39.7)	1011 (36.5)	1389 (37.3)
	Missing	3 (0.3)	1 (0.04)	4 (0.1)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Regions of study hospitals (n, %) [2]	East	360 (37.8)	1330 (48.0)	1690 (45.4)
	Central	208 (21.8)	717 (25.9)	925 (24.8)
	West	385 (40.4)	725 (26.2)	1110 (29.8)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Clinical settings (n, %)	Inpatient	837 (87.8)	2400 (86.6)	3237 (86.9)
	Outpatient	116 (12.2)	372 (13.4)	488 (13.1)

The denominator is the number of patients in each group within V260-080 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 14.6.3. Demographic and clinical characteristics of RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1) *(Continued)*

		Case Group (RV +) N (%)	*Control Group (RV -) N (%)*	*Total N (%)*
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Symptom onset seasons (n, %) [3]	2020/10-2021/3	372 (39.0)	202 (7.3)	574 (15.4)
	2021/10-2022/4	133 (14.0)	962 (34.7)	1095 (29.4)
	2022/10-2023/4	102 (10.7)	792 (28.6)	894 (24.0)
	2024/10-2025/4	346 (36.3)	816 (29.4)	1162 (31.2)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Gender (n, %)	Male	593 (62.2)	1686 (60.8)	2279 (61.2)
	Female	360 (37.8)	1086 (39.2)	1446 (38.8)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
College and above for either parent's education level (n, %)	No	198 (20.8)	880 (31.7)	1078 (28.9)
	Yes	378 (39.7)	1668 (60.2)	2046 (54.9)
	Missing	377 (39.6)	224 (8.1)	601 (16.1)
	Total	953 (100.0)	2772 (100.0)	3725 (100.0)
Number of doses intervals greater than 10 weeks	One dose interval > 10 weeks and one dose interval <= 10 weeks	10 (90.9)	163 (99.4)	173 (98.9)
	Both dose intervals > 10 weeks	1 (9.1)	1 (0.6)	2 (1.1)
	Total	11 (100.0)	164 (100.0)	175 (100.0)

The denominator is the number of patients in each group within V260-080 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 14.6.4. Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Age of onset (in months) (Continuous)	0.026	<0.001	1.026 (1.021, 1.032)
Birth seasons (RV peak season vs Non-RV peak season)	0.035	0.645	1.036 (0.892, 1.202)
Residence location (Urban vs Rural)	-0.140	0.069	0.869 (0.747, 1.011)
Regions of study hospitals (Central vs East)	0.069	0.483	1.072 (0.883, 1.300)
Regions of study hospitals (West vs East)	0.674	<0.001	1.962 (1.656, 2.325)
Clinical setting (Inpatient vs Outpatient)	0.112	0.325	1.118 (0.895, 1.398)
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4)	1.468	<0.001	4.343 (3.511, 5.371)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-1.121	<0.001	0.326 (0.262, 0.407)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-1.191	<0.001	0.304 (0.239, 0.387)
Gender (Male vs Female)	0.059	0.444	1.061 (0.912, 1.235)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.684	<0.001	0.186 (0.100, 0.343)

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 14.6.5. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.036	<0.001	1.037 (1.031, 1.043)	
Residence location (Urban vs Rural) [1]	-0.207	0.022	0.813 (0.682, 0.970)	
Regions of study hospitals (Central vs East) [1]	0.245	0.029	1.278 (1.025, 1.592)	
Regions of study hospitals (West vs East) [1]	0.816	<0.001	2.260 (1.852, 2.759)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.673	<0.001	5.329 (4.231, 6.713)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	-0.910	<0.001	0.402 (0.318, 0.508)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-1.192	<0.001	0.304 (0.236, 0.391)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.685	<0.001	0.185 (0.097, 0.356)	81.45% (64.40%, 90.34%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.4, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 3721 (including 950 cases and 2771 controls).
Sensitivity analysis 1: Assuming that all children without confirmed vaccination information were unvaccinated.

Table 14.6.6. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.036	<0.001	1.037 (1.031, 1.043)	
Residence location (Urban vs Rural) [2]	-0.195	0.032	0.823 (0.689, 0.983)	
Regions of study hospitals (Central vs East) [2]	0.233	0.040	1.262 (1.010, 1.576)	
Regions of study hospitals (West vs East) [2]	0.818	<0.001	2.267 (1.855, 2.770)	
Symptom onset seasons (2020/10-2021/3 vs 2024/10-2025/4) [1]	1.679	<0.001	5.359 (4.251, 6.756)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	-0.874	<0.001	0.417 (0.329, 0.529)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-1.182	<0.001	0.307 (0.238, 0.396)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [1]	-1.700	<0.001	0.183 (0.095, 0.351)	81.73% (64.93%, 90.48%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Age of onset (in months), symptom onset seasons, received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 are the fixed variables in the logistic regression.
[2] Refer to the results of table 8.4.4, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 3614 (including 940 cases and 2674 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 >= 0.1.

Table 14.6.7.1. Conditional Univariate Logistic Regression (G1/G2/G3/G4/G9--Sensitivity analysis 3-1:1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.131	0.279	0.878 (0.693, 1.112)
Residence location (Urban vs Rural)	0.089	0.465	1.093 (0.861, 1.388)
Regions of study hospitals (Central vs East)	0.100	0.508	1.105 (0.822, 1.487)
Regions of study hospitals (West vs East)	0.562	<0.001	1.754 (1.342, 2.292)
Clinical setting (Inpatient vs Outpatient)	0.521	0.011	1.684 (1.127, 2.516)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.609	<0.001	0.200 (0.089, 0.450)

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 seasons).
1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.6.7.2. Conditional Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 3-1:2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.059	0.588	0.943 (0.762, 1.166)
Residence location (Urban vs Rural)	*		
Regions of study hospitals (Central vs East)	0.104	0.463	1.109 (0.841, 1.463)
Regions of study hospitals (West vs East)	0.639	<0.001	1.896 (1.486, 2.418)
Clinical setting (Inpatient vs Outpatient)	0.550	0.003	1.734 (1.210, 2.485)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.712	<0.001	0.180 (0.086, 0.379)

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 seasons).
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 14.6.7.3. Conditional Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 3-1:3)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	-0.074	0.479	0.929 (0.756, 1.140)
Residence location (Urban vs Rural)	0.106	0.316	1.111 (0.904, 1.366)
Regions of study hospitals (Central vs East)	0.070	0.608	1.072 (0.822, 1.399)
Regions of study hospitals (West vs East)	0.713	<0.001	2.041 (1.610, 2.586)
Clinical setting (Inpatient vs Outpatient)	0.416	0.022	1.516 (1.063, 2.161)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.691	<0.001	0.184 (0.089, 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 seasons).
1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.8.1. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 3-1:1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Regions of study hospitals (Central vs East) [1]	0.053	0.732	1.055 (0.777, 1.432)	
Regions of study hospitals (West vs East) [1]	0.682	<0.001	1.977 (1.491, 2.622)	
Clinical setting (Inpatient vs Outpatient) [1]	0.622	0.004	1.863 (1.223, 2.838)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.868	<0.001	0.154 (0.067, 0.355)	84.55% (64.48%, 93.28%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.7.1, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 1134 (including 567 cases and 567 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 seasons).
1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.6.8.2. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 3-1:2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Regions of study hospitals (Central vs East) [1]	0.038	0.790	1.039 (0.784, 1.377)	
Regions of study hospitals (West vs East) [1]	0.748	<0.001	2.113 (1.640, 2.724)	
Clinical setting (Inpatient vs Outpatient) [1]	0.639	<0.001	1.894 (1.303, 2.754)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.975	<0.001	0.139 (0.065, 0.297)	86.13% (70.27%, 93.53%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.7.2, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 1554 (including 567 cases and 987 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 seasons).
1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.6.8.3. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 3-1:3)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Regions of study hospitals (Central vs East) [1]	0.021	0.876	1.022 (0.780, 1.338)	
Regions of study hospitals (West vs East) [1]	0.823	<0.001	2.276 (1.781, 2.909)	
Clinical setting (Inpatient vs Outpatient) [1]	0.517	0.005	1.678 (1.167, 2.412)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.964	<0.001	0.140 (0.066, 0.297)	85.96% (70.28%, 93.37%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.7.3, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 1897 (including 567 cases and 1330 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 seasons).
1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.9.1. Conditional Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 4-1:1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	0.010	0.921	1.010 (0.832, 1.226)
Residence location (Urban vs Rural)	-0.281	0.004	0.755 (0.623, 0.915)
Regions of study hospitals (Central vs East)	0.273	0.027	1.314 (1.031, 1.673)
Regions of study hospitals (West vs East)	0.626	<0.001	1.871 (1.516, 2.309)
Clinical setting (Inpatient vs Outpatient)	0.341	0.013	1.407 (1.075, 1.840)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.627	<0.001	0.196 (0.103, 0.375)

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, onset date).
1:1 match (1 case matched up to 1 control) was used to allow the utmost of matched pairs.

Table 14.6.9.2. Conditional Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 4-1:2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	0.027	0.752	1.028 (0.868, 1.217)
Residence location (Urban vs Rural)	-0.207	0.014	0.813 (0.688, 0.959)
Regions of study hospitals (Central vs East)	0.151	0.159	1.163 (0.943, 1.435)
Regions of study hospitals (West vs East)	0.627	<0.001	1.871 (1.554, 2.253)
Clinical setting (Inpatient vs Outpatient)	0.364	0.003	1.439 (1.130, 1.833)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.552	<0.001	0.212 (0.112, 0.399)

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, onset date).
1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.6.9.3. Conditional Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 4-1:3)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Birth seasons (RV peak season vs Non-RV peak season)	0.007	0.933	1.007 (0.854, 1.188)
Residence location (Urban vs Rural)	-0.174	0.033	0.840 (0.716, 0.986)
Regions of study hospitals (Central vs East)	0.150	0.149	1.162 (0.947, 1.426)
Regions of study hospitals (West vs East)	0.666	<0.001	1.946 (1.623, 2.332)
Clinical setting (Inpatient vs Outpatient)	0.339	0.005	1.403 (1.106, 1.781)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.642	<0.001	0.194 (0.104, 0.361)

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, onset date).
1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.10.1. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 4-1:1)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Residence location (Urban vs Rural) [1]	-0.333	0.001	0.717 (0.584, 0.880)	
Regions of study hospitals (Central vs East) [1]	0.207	0.105	1.230 (0.958, 1.579)	
Regions of study hospitals (West vs East) [1]	0.759	<0.001	2.137 (1.711, 2.670)	
Clinical setting (Inpatient vs Outpatient) [1]	0.418	0.004	1.518 (1.139, 2.024)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.739	<0.001	0.176 (0.091, 0.341)	82.43% (65.93%, 90.93%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.9.1, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 1880 (including 940 cases and 940 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, onset date).
1:1 match (1 case matched up to 1 control) was used to allow the utmost matched pairs.

Table 14.6.10.2. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 4-1:2)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Residence location (Urban vs Rural) [1]	-0.250	0.005	0.778 (0.654, 0.927)	
Regions of study hospitals (Central vs East) [1]	0.110	0.316	1.116 (0.901, 1.383)	
Regions of study hospitals (West vs East) [1]	0.746	<0.001	2.108 (1.738, 2.557)	
Clinical setting (Inpatient vs Outpatient) [1]	0.495	<0.001	1.640 (1.271, 2.117)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.633	<0.001	0.195 (0.102, 0.373)	80.46% (62.74%, 89.75%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.9.2, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 2658 (including 940 cases and 1718 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, onset date).
1:2 match (1 case matched up to 2 controls) was used to allow the utmost of matched pairs.

Table 14.6.10.3. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 4-1:3)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Residence location (Urban vs Rural) [1]	-0.217	0.011	0.805 (0.680, 0.952)	
Regions of study hospitals (Central vs East) [1]	0.111	0.298	1.117 (0.906, 1.377)	
Regions of study hospitals (West vs East) [1]	0.786	<0.001	2.196 (1.819, 2.651)	
Clinical setting (Inpatient vs Outpatient) [1]	0.483	<0.001	1.621 (1.261, 2.084)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.736	<0.001	0.176 (0.094, 0.332)	82.37% (66.80%, 90.64%)

Dependent variable (Case Group vs Control Group). Conditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.9.3, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Conditional multivariate logistic regression was performed using a sample size of 3074 (including 940 cases and 2134 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, onset date).
1:3 match (1 case matched up to 3 controls) was used to allow the utmost of matched pairs.

Table 14.6.11. Univariate Logistic Regression (G1/G2/G3/G4/G9-Sensitivity analysis 5)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*
Age of onset (in months) (Continuous)	0.038	<0.001	1.039 (1.033, 1.045)
Birth seasons (RV peak season vs Non-RV peak season)	0.004	0.969	1.004 (0.834, 1.207)
Residence location (Urban vs Rural)	0.055	0.569	1.057 (0.874, 1.278)
Regions of study hospitals (Central vs East)	-0.108	0.379	0.898 (0.706, 1.142)
Regions of study hospitals (West vs East)	0.451	<0.001	1.570 (1.274, 1.936)
Clinical setting (Inpatient vs Outpatient)	0.377	0.024	1.457 (1.052, 2.019)
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4)	-1.089	<0.001	0.337 (0.269, 0.422)
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4)	-1.186	<0.001	0.305 (0.239, 0.390)
Gender (Male vs Female)	0.176	0.070	1.193 (0.986, 1.443)
College and above for either parent's education level (Yes vs No)	-0.003	0.976	0.997 (0.823, 1.208)
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (Yes vs No)	-1.583	<0.001	0.205 (0.100, 0.420)

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 14.6.12. Adjusted vaccine effectiveness against RVGE cases due to G1/G2/G3/G4/G9 types (Sensitivity analysis 5)

Factors	*Regression Coefficient*	*P Value*	*OR (95% CI)*	*VE (%, 95% CI)*
Age of onset (in months) (Continuous) [1]	0.035	<0.001	1.036 (1.029, 1.042)	
Regions of study hospitals (Central vs East) [1]	0.066	0.615	1.068 (0.826, 1.382)	
Regions of study hospitals (West vs East) [1]	0.753	<0.001	2.123 (1.691, 2.665)	
Clinical setting (Inpatient vs Outpatient) [1]	0.526	0.003	1.692 (1.196, 2.393)	
Symptom onset seasons (2021/10-2022/4 vs 2024/10-2025/4) [1]	-0.853	<0.001	0.426 (0.336, 0.541)	
Symptom onset seasons (2022/10-2023/4 vs 2024/10-2025/4) [1]	-1.149	<0.001	0.317 (0.246, 0.409)	
Gender (Male vs Female) [1]	0.187	0.072	1.206 (0.984, 1.478)	
Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 (fixed variable, Yes vs No) [2]	-1.868	<0.001	0.155 (0.073, 0.325)	84.55% (67.49%, 92.66%)

Dependent variable (Case Group vs Control Group). Unconditional multivariate logistic regression was used.
[1] Refer to the results of table 8.6.11, potential confounders which are significantly different (P < 0.1) between case and controls group will be included in model.
[2] Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks between 1 and 2 and/or 2 and 3 is the fixed variable in the logistic regression.
VE was calculated by one minus the odds ratio for "Received ROTATEQ vaccination with at least one dosing intervals greater than 10 weeks".
Unconditional multivariate logistic regression was performed using a sample size of 3022 (including 567 cases and 2455 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.