



# Validation of parental reports of rotavirus vaccination of their children compared to the national immunization registry



Shayel Bercovich<sup>a</sup>, Emilia Anis<sup>b</sup>, Eias Kassem<sup>c</sup>, Uri Rubinstein<sup>d</sup>, Moshe Ephros<sup>e,f</sup>, Dani Cohen<sup>a</sup>,  
Khitam Muhsen<sup>a,\*</sup>

<sup>a</sup> Department of Epidemiology and Preventive Medicine, School of Public Health, Sackler Faculty of Medicine, Tel Aviv University, Ramat Aviv, Tel Aviv, Israel

<sup>b</sup> Division of Epidemiology, Ministry of Health, Jerusalem, Israel

<sup>c</sup> Department of Pediatrics, Hillel Yaffe Medical Center, Hadera, Israel

<sup>d</sup> Department of Pediatrics, Laniado Medical Center, Netanya, Israel

<sup>e</sup> Department of Pediatrics, Carmel Medical Center, Haifa, Israel

<sup>f</sup> Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel

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## ABSTRACT

**Background:** The introduction of rotavirus vaccines into national immunization programs necessitates vaccine effectiveness evaluations. Parental report of vaccination status is a simple and accessible source of information; however, its validity is unclear.

**Aims:** To validate parental reports of rotavirus immunization compared to documentation of vaccination in national immunization registry, and to assess vaccine effectiveness by each method.

**Methods:** Parents of 1272 children aged 2–59 months from northern Israel hospitalized for gastroenteritis in 2011–2015 were interviewed on the sociodemographics and rotavirus vaccination status of their child. Rotavirus immunization status based on parental report was compared to that documented in the national immunization registry, which was considered the gold standard. Stool samples collected from patients were tested for rotavirus antigen by immunochromatography. In a rotavirus test-negative case-control study, vaccination history was compared between children found positive for rotavirus and those who tested negative. Vaccine effectiveness for  $\geq 1$  dose vs. zero doses was calculated as:  $(1 - \text{adjusted odds ratio}) * 100$ .

**Results:** The sensitivity and specificity of parental report of their child's immunization with a rotavirus vaccine were 97% (95% CI 96–98), and 75% (95% CI 65–82), respectively. Kappa coefficient was 0.69 ( $p < 0.001$ ) for the agreement between the two methods. Rotavirus vaccine effectiveness was 72% (95% CI 54–84) when using parental report of rotavirus immunization and 79% (95% CI 62–88) when using the registry.

**Conclusion:** Parental report of their child's immunization with a rotavirus vaccine demonstrated high sensitivity, although the specificity was relatively low. Vaccine effectiveness was similar regardless of method used to determine rotavirus immunization status. Parental report of vaccination status can be useful in vaccine effectiveness assessment.

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## 1. Introduction

Parental reports of their children's health status is an integral part of pediatric medical care, thus understanding the validity of

such reports is highly important. Low maternal education and longer time since medical procedure of interest were shown to negatively affect the accuracy of maternal reports, while accuracy of the reports was higher on significant procedures such as major surgery than minor procedures [1,2]. Social reasons, such as embarrassment, concern of being stigmatized as a neglecting parent might also affect parental report [3,4].

Information on immunization status is important from both clinical and public health perspectives. Common information sources on vaccination status include medical records, national registries, serological assays and parental reports [5–7]. Of these,

*Abbreviations:* bOPV, bivalent oral polio vaccine; CI, confidence intervals; DTP, diphtheria, tetanus, pertussis; MMR, measles, mumps, rubella; OR, odds ratio; RVGE, rotavirus gastroenteritis; SD, standard deviation; SES, socioeconomic status.

\* Corresponding author at: Department of Epidemiology and Preventive Medicine, School of Public Health, Sackler Faculty of Medicine, Tel Aviv University, Ramat Aviv, Tel Aviv 69978, Israel.

E-mail address: [kmhsen@post.tau.ac.il](mailto:kmhsen@post.tau.ac.il) (K. Muhsen).

parental reports is a simple and accessible source [8]; however, limited evidence exists regarding the validity of parental reports of vaccination status compared to national registries or vaccination cards. Such information can be useful in clinical decision-making as well as in evaluating vaccine coverage and vaccine effectiveness [9–12].

Rotavirus immunization with RotaTeq was added to the national immunization program in Israel in December 2010. The vaccine is given, at no cost to parents, at ages 2, 4 and 6 months [13–16]. The aim of this study was to assess the validity of parental report of rotavirus immunization status compared to documentation in national immunization registry. We also explored whether rotavirus vaccine effectiveness differs by the method of classification of rotavirus immunization status.

## 2. Materials and methods

### 2.1. Study population and design

This validation study was undertaken in the framework of an active surveillance of hospitalizations RVGE from November 2007 through February 2016 [13–15,17,18] in three hospitals in northern Israel: Hillel Yaffe in Hadera, Laniado in Netanya and Carmel in Haifa. The population living in the areas of the study hospitals reflect the ethnic diversity of the Israeli Jewish and Arab populations.

The current study was limited to children aged 2–59 months born in 2011–2015 who were eligible to receive rotavirus vaccine in the framework of the universal national immunization program, and for whom information on rotavirus immunization was obtained. The vaccine is given at ages 2, 4 and 6 months [13–16] at maternal and child health clinics run by the Ministry of Health and located throughout the country.

In August 2013, a supplemental bOPV was given to children aged <10 years, in response to the silent re-introduction and transmission of wild poliovirus type 1 in Israel. In January 2014 the bOPV was added to the national immunization program in Israel supplemental to the inactivated polio vaccine, given at ages 6 and 18 months [19,20].

Children hospitalized with diarrhea (three or more watery stools during a 24-hours period) were tested for rotavirus antigen in stool samples using immunochromatography. Parents were interviewed for demographic variables (child's sex, age in months [categorized 2–5, 6–11, 12–23 and 24–59 months] and population group) and rotavirus vaccination history, using a modified questionnaire of World Health Organization generic protocol questionnaires [21].

Specifically parents were asked, “Did your child receive a rotavirus vaccine? The answers were yes or no”. Parents who answered yes were asked “Which vaccine? RotaTeq or Rotarix?”. Parents were then asked to specify the number of doses and when each dose was given. The question on the vaccine type was added since during the pre-universal years of rotavirus immunization programs both vaccines were available in the private market. The current analysis was limited to children who were eligible for rotavirus immunization in the framework of universal immunization program using RotaTeq.

Additionally, information on rotavirus vaccine was obtained through linkage with the national immunization registry at the Ministry of Health, about one year after completing the field data collection (i.e. enrollment and parental interviews in the study hospitals). Upon immunization at the maternal and child health clinics, this information is documented by the nurses in electronic records, and automatically transferred to the registry [22,23]. Thus, a scenario in which a child received the vaccine but this was not documented in the registry due to lag time is unlikely.

Herein we compared the child's rotavirus immunization status as defined by parental report to that documented in the national immunization registry, which was considered the gold standard. Children were classified as unvaccinated or vaccinated with at least one dose, and according to the number of doses. Children listed on the registry with no doses of rotavirus vaccine, were classified as unvaccinated children, with zero doses of rotavirus vaccine. SES was classified according to the socioeconomic rank of the town of residence [24]. The ranks were grouped as low SES (ranks 1–3) and high SES (ranks 4–10).

### 2.2. Statistical analysis

Chi square test was used to examine differences in sociodemographic characteristics, between children with complete data on rotavirus vaccination status and children who had missing data on immunization status. Sensitivity and specificity were calculated for vaccination status (yes/no) based on parental reports of rotavirus immunization, while using the national immunization registry as the gold standard. Ninety five percent CI for sensitivity and specificity were produced using the Wilson score method [25]. This analysis included data of 1092 children with complete information on rotavirus immunization status.

Kappa coefficient was calculated to determine the agreement beyond chance between parental reports and the national registry data. Additional analyses were performed in stratification by children's age group, population group, residential SES and year of hospitalization, (categorized as 2011–2012 [prior to the silent polio outbreak] vs. 2013–2015). Heterogeneity of the sensitivity and specificity was assessed using the chi square test for heterogeneity according to these variables.

We further assessed the associations between sociodemographic factors and inaccurate report of rotavirus immunization defined as discordance between parental report and immunization registry, using chi square test and logistic regression model. The variables population group and residential SES were highly correlated, therefore they were included in separate models.

In a test-negative case-control study of 703 children who were tested for rotavirus, we fitted logistic regression models, in which RVGE was the dependent variable (cases were children who tested positive for rotavirus and children with diarrhea who tested negative for rotavirus comprised the control group). Adjusted OR and 95% CI for rotavirus immunization status were obtained from the models that included vaccination status (in one model via linkage to the national immunization registry and in another model through parental reports), age, sex, population group and residential SES. Vaccine effectiveness for being immunized with at least one dose compared to no immunization, was calculated as  $(1 - \text{adjusted OR}) * 100$  [26].

### 2.3. Ethical aspects

The study protocol was approved by Institutional Review Boards of all participating hospitals and the Ministry of Health. Parents signed a written informed consent form.

## 3. Results

Overall, 1272 children aged 2–59 months (mean age 12.8 [SD] 9.3) were hospitalized due to gastroenteritis during 2011–2015, among those 54% were males and 38% were Arabs. Information on rotavirus immunization status according to both parental reports and the national immunization registry was available for 1092 (86%) children. There was no significant difference between children with complete immunization data vs. those with missing

data in sex, however the former included a significantly higher percentage of Arab children (42% vs. 15%), residents of low SES communities (35% vs. 8%) and infants (23% vs. 13%) (Supplementary table 1).

### 3.1. Comparison between classification of rotavirus immunization status according to parental reports and national immunization registry

Based on parental reports, 992 (91%) children were immunized with at least one dose of RotaTeq, and 998 (91%) according to the national immunization registry. Among children who were vaccinated with RotaTeq based on the national immunization registry, 968 were also classified as immunized based on parental reports, yielding a sensitivity of 97% (95% CI 96–98). Among 94 children who were not vaccinated with RotaTeq based on the national immunization registry, 70 were also classified as not vaccinated according to parental reports, yielding a specificity of 75% (95% CI 65–82). A false negative of 3% was demonstrated for 30

vaccinated children, reported unvaccinated by their parents. A false positive result was demonstrated for 24 (25%) children reported as vaccinated by their parents. Kappa coefficient was 0.69 ( $p < 0.001$ ) for the agreement between the two methods for classifying rotavirus immunization status (Table 1).

Stratification by demographic factors showed limited effect on the sensitivity (94%–98%) of parental reports of rotavirus immunization. The specificity decreased from 90% at age 2–5 months to 50% at age 24–59 months (Table 2) ( $P = 0.01$  for heterogeneity by age group). No significant heterogeneity was noted according to other demographic factors.

### 3.2. Rotavirus vaccination status discordance

There was no significant difference between children with discordant rotavirus vaccination status vs. those with concordant status in sex, age, residential SES and population group, however the discordant group included a lower percentage of children who were admitted during 2013–2015 than the concordant group

**Table 1**

Comparison between parental reports of RotaTeq vaccination and documentation in the national immunization registry by socio-demographic variables.

	Vaccinated parental reports/registry	Unvaccinated parental reports/registry	Sensitivity <sup>*</sup> (95% CI)	Specificity <sup>*</sup> (95% CI)	Kappa <sup>**</sup>
<b>All children</b>	968/998	70/94	97% (96–98)	75% (65–82)	0.69
<b>Age group</b>					
2–5 months	204/216	35/39	94% (91–97)	90% (76–96)	0.78
6–11 months	321/331	19/26	97% (94–98)	73% (54–86)	0.66
12–23 months	325/331	11/19	98% (96–99)	58% (36–77)	0.59
24–59 months	118/120	5/10	98% (94–99)	50% (24–76)	0.56
<b>Admission year</b>					
2011–2012	251/263	20/29	95% (92–97)	69% (50–83)	0.62
2013–2015	717/735	50/65	98% (96–99)	77% (65–85)	0.72
<b>Residential SES</b>					
Low	336/350	22/31	96% (93–98)	71% (53–84)	0.62
High	627/643	47/62	98% (96–99)	76% (64–85)	0.73
<b>Population group</b>					
Jews	568/582	42/55	98% (96–99)	76% (64–86)	0.73
Arabs	400/416	28/39	96% (94–98)	72% (56–83)	0.64

CI: confidence intervals SES: socioeconomic status of place residence

<sup>\*</sup> Specificity: the number of children who did not receive rotavirus vaccine according to parental report divided by the number of children who did not receive rotavirus vaccine according to registry \*100.

<sup>\*</sup> Sensitivity: the number of children who received rotavirus vaccine according to parental report divided by the number of children who received rotavirus vaccine according to registry \*100.

<sup>\*\*</sup> P value < 0.001 for all Kappa coefficients

**Table 2**

Comparison between children with concordant vs. discordant rotavirus vaccination status from both parental reports and national immunization registry.

	Concordant vaccination status	Discordant vaccination status	P-value <sup>*</sup>	aOR (95%CI)	P-value <sup>**</sup>
<b>Total</b>	1038 (95%)	54 (5%)			
<b>Sex</b>			0.3		0.3
Male	553 (53%)	32 (59%)		0.78 (0.45–1.37)	
Female	485 (47%)	22 (41%)		Reference	
<b>Age group</b>			0.6		0.7
2–5 months	239 (23%)	16 (29%)		Reference	
6–11 months	340 (33%)	17 (32%)		0.78 (0.38–1.59)	0.4
12–23 months	336 (32%)	14 (26%)		0.74 (0.34–1.58)	0.4
24–59 months	123 (12%)	7 (13%)		1.16 (0.44–3.06)	0.7
<b>Admission year</b>			0.039		0.05
2011–2012	271 (26%)	21 (39%)		Reference	
2013–2015	767 (74%)	33 (61%)		0.55 (0.30–1.00)	
<b>Residential SES</b>			0.2		0.3
Low	358 (35%)	23 (43%)		Reference	
High	674 (65%)	31 (57%)		0.75 (0.43–1.33)	
<b>Population group</b>			0.2		0.2
Jews	610 (59%)	27 (50%)		Reference	
Arabs	428 (41%)	27 (50%)		1.35 (0.77–2.36)	

aOR: adjusted odds ratio, CI: confidence intervals, SES: socioeconomic status

The variables population group and socioeconomic status were included in separate models, given the high correlation between them (Phi correlation coefficient = 0.8).

<sup>\*</sup> P value obtained by chi square test.

<sup>\*\*</sup> P value from multivariable logistic regression model that adjusted for the variables in the table.

(74% vs. 61%,  $P = 0.039$ ). The results were similar in a multivariable model (Table 2).

### 3.3. Comparison between parental reports of the number of RotaTeq doses and the national immunization registry data

Information on the number of RotaTeq doses based on both the registry and parental report was available for 1056 children. Overall Kappa coefficient for the agreement on the number of doses (including children who were not immunized with any dose) was 0.72,  $p < 0.01$ . Stratification by the following age groups: 2–3, 4–5 and 6–59 months representing children who were eligible to receive one, two and three doses, respectively, in the framework of the universal immunization program, showed fair to good agreement between parental reports and the immunization registry on the number of vaccine doses the child had received, with respective Kappa coefficients of 0.70, 0.57 and 0.62 (Table 3).

### 3.4. Vaccine effectiveness according to the classification method of vaccination status

Rotavirus was tested among 703 (64%) children with available data on immunization status based on both the national registry and parental reports. Rotavirus was detected among 96 (14%) children, and the rest 607 (86%) tested negative. The percentages of Jewish children, those who lived in high SES towns and children admitted during 2013–2015 were significantly higher among patients with RVGE than the control group as shown in the bivariate analysis. No significant differences between the groups were noted in sex and age (Table 4).

Parents of 75 (78%) RVGE cases reported that their child received at least one dose of a rotavirus vaccine, compared to 71 (74%) when using the registry data. The respective figures in the control group were 552 (91%) and 546 (90%) ( $p < 0.001$ ). A multivariable analysis that included rotavirus vaccination status based on parental report and adjusted for age (as a categorical variable), sex, population group, and year of admission showed an inverse association between the vaccine and RVGE: adjusted OR 0.28 (95% CI 0.16–0.51),  $p < 0.001$ . This yielded a vaccine effectiveness of 72% (95% CI 49–84). Another model in which we included the variable of rotavirus immunization according to the registry data and adjusting for the aforementioned variables showed adjusted

**Table 4**  
Factors associated with RVGE.

	RVGE n = 96	Controls n = 607	P value
<b>Sex</b>			0.6
Male	53 (55%)	321 (53%)	
Female	43 (45%)	286 (47%)	
<b>Age group</b>			0.068
2–5 months	15 (16%)	164 (27%)	
6–11 months	33 (34%)	202 (33%)	
12–23 months	39 (41%)	183 (30%)	
24–59 months	9 (9%)	58 (10%)	
<b>Admission year</b>			0.017
2011–2012	17 (18%)	179 (30%)	
2013–2015	79 (82%)	428 (70%)	
<b>Residential SES</b>			0.007
Low	19 (20%)	203 (34%)	
High	77 (80%)	400 (66%)	
<b>Population group</b>			0.004
Jews	73 (76%)	369 (61%)	
Arabs	23 (24%)	238 (39%)	
<b>Rotavirus vaccination by parental reports</b>	75 (78%)	552 (91%)	<0.001
<b>Rotavirus vaccination by registry</b>	71 (74%)	547 (90%)	<0.001

SES: socioeconomic status. RVGE: rotavirus gastroenteritis. Controls: children with gastroenteritis who tested negative for rotavirus

P value obtained by chi square test

OR 0.21 (95% CI 0.12–0.37),  $p < 0.001$ , and vaccine effectiveness of 79% (95% CI 62–88). The results were similar in models that included the variables residential SES instead of population group (Table 5).

## 4. Discussion

We validated parental reports of rotavirus immunization compared to documentation of vaccination in national immunization registry, and assessed vaccine effectiveness by both methods used to determine immunization status.

Overall the sensitivity of parental reports of rotavirus immunization status of their child was high 97% (95% CI 96–98) compared to the national registry data, however the specificity was lower 75% (95% CI 65–82). This implies parental over-reporting on their child's immunization with a rotavirus vaccine; a false pos-

**Table 3**  
Comparison between parental reports of the number of RotaTeq doses and the national immunization registry data.

Age, months		Number of doses	Registry				Total	Kappa
			0	1	2	3		
2–3	Parental report	0	31	10			41	0.70
		1	5	84			89	
		2	0	2			2	
		3	0	0			0	
	Total		36	96			132	
4–5	Parental report	0	4	0	2		6	0.57
		1	0	34	0		34	
		2	0	22	52		74	
		3	0	1	3		4	
	Total		4	57	57		118	
6–59	Parental report	0	35	3	7	7	52	0.62
		1	0	4	0	0	4	
		2	2	1	61	5	69	
		3	17	5	55	604	681	
	Total		54	13	123	616	806	
Total	Parental report	0	70	13	9	7	99	0.72
		1	5	122	0	0	127	
		2	2	25	113	5	145	
		3	17	6	58	604	685	
	Total		94	166	180	616	1056	

Data presented are absolute numbers

**Table 5**

Association of immunization with at least one dose of RotaTeq and hospitalization for RVGE in children 2–59 months of age.

	OR (95% CI) <sup>a</sup>	P value <sup>a</sup>	Vaccine effectiveness (95% CI)
<b>Rotavirus vaccination by parental reports with ≥ 1 dose (reference: no immunization)</b>			
Unadjusted	0.36 (0.20–0.62)	<0.001	64% (38–80)
Adjusted model 1 <sup>**</sup>	0.28 (0.16–0.51)	<0.001	72% (49–84)
Adjusted model 2 <sup>**</sup>	0.27 (0.15–0.50)	<0.001	73% (50–85)
<b>Rotavirus vaccination by registry with ≥ 1 dose (reference: no immunization)</b>			
Unadjusted	0.31 (0.18–0.53)	<0.001	69% (47–82)
Adjusted model 1 <sup>**</sup>	0.21 (0.12–0.37)	<0.001	79% (63–88)
Adjusted model 2 <sup>**</sup>	0.21 (0.11–0.38)	<0.001	79% (62–89)

Vaccine effectiveness was calculated as  $(1-OR)^*100$ , for vaccination with least one dose vs. no vaccination<sup>a</sup> CI: confidence intervals; OR: odds ratio; P value was obtained from logistic regression models.<sup>\*\*</sup> Model 1 included the variables: rotavirus immunization with at least one dose of RotaTeq vs. no immunization, sex, age (as a categorical variable 2–5, 6–11, 12–23 and 24–59 months), and population group and admission year. Model 2 included the same variables, but included residential socioeconomic status instead of population group.

itive result was found in 24 (25%) of the unvaccinated children. The reason of over-reporting might be parental embarrassment to report to medical personnel that their child is unvaccinated, lack of specific knowledge on rotavirus vaccination or both. We also found a small percentage of parents (3%) who reported that their child was unvaccinated with a rotavirus vaccine, while according to the registry the child received the vaccine. This likely reflects lack of knowledge regarding the specific vaccines the child had received. These findings emphasize the need of obtaining information from parents on their child's vaccination history in a non-judgmental manner to receive a reliable picture, and educating parents on specific vaccines. Moreover, parental reports of immunization with a rotavirus vaccine yielded a vaccine coverage estimate close to the truth. Our findings may be generalizable to populations in high-income and middle-income countries, while generalizability to populations in low-income countries might be limited.

A study conducted among parents of 1029 children aged less than two years in Texas, showed that only 34% of parents accurately recalled the number of shots of DTP vaccine a child received compared to medical records, while 42% reported lower vaccination coverage than the medical records with similar findings shown for OPV. On the other hand, a higher accuracy was found for MMR vaccine, for which 83% of the parents reported correctly the immunization status of their child [27]. A study conducted among mothers of children aged less than three years from Costa Rica showed a strong correlation ( $r=0.71$ ) between maternal reports and documentation in immunization records. Errors in maternal recall for measles, polio, and DTP vaccines were inversely related to the actual number of vaccination doses [9].

Our results are in agreement with other reports showing good concordance between parental reports and vaccination cards (Kappa  $\geq 0.90$  [10,28] and correlation coefficient 0.71 [9]) for OPV, DTP, and other injectable vaccines, and high sensitivity and specificity (87% and 79% respectively) [11].

Stratification by demographic variables showed limited effect on the ability of parents to correctly recall that their child was indeed immunized with a rotavirus vaccine; sensitivity (94%–98%). However, significant heterogeneity in the specificity was noted according to age group, with consistent decline in specificity and Kappa coefficient with increased age. The child's age is a proxy of the time since the vaccine was administered. As RotaTeq is administered no later than age eight months, this questions the ability of parents to recall accurately their child's vaccinations as time passes. This observation is in agreement with previous studies [9,27]. This could be due to additional influencing factors such as mix-up with bOPV given in two doses at ages 6 and 18 months.

Interestingly, our evaluation of the RotaTeq effectiveness against RVGE hospitalization, yielded similar results regardless of the sources of information employed to determine the child's immunization status. Effectiveness of RotaTeq vaccine was 72% (95% CI 49–84) when parental report was used, and 79% (95% CI 62–88) when immunization registry was used. The similarity in effectiveness despite the low specificity for parental reports is due to non-differential misclassification of the child's immunization status. If parents of RVGE cases and controls remember or report rotavirus immunization in a different manner, this would have affected the vaccine effectiveness estimates. This observation reinforces the utility of using parental report of rotavirus immunization status in vaccine effectiveness studies. This might be applicable to other vaccines as well. However, parental recall remains limited by the inability of parents to remember the exact date of the child immunization. This is important since some vaccine effectiveness studies use a 14-day interval between vaccination and symptom onset to determine the vaccine effectiveness. In theory, it is possible to complete immunization date from the child's immunization card. However, in acute illnesses and hospitalizations settings it is likely that parents will not bring the child's immunization card to the hospital, which was the case in our study. From a clinical perspective, when individual care is delivered, reliance on parental reports should be done with caution considering its low specificity when compared to registry data.

Our study has strengths. The study was conducted during a five-year period after introducing universal rotavirus immunization using an unselected sample, given the high accessibility to health care in Israel including vaccines in the national immunization program. The study included children of various age and population groups, as well as socioeconomic backgrounds, which increases the generalizability of our results.

Our study has also limitations. The study was conducted among hospitalized children and it might be that parents of a hospitalized child remember or report medical information differently than parents of non-hospitalized children. However, this can also be regarded as a strength since it mirrors real-life clinical situation in pediatric care. We examined the validity of parental reports of one oral vaccine; which might differ for injectable vaccines. The oral route of vaccine administration cannot explain the high sensitivity of parental reports since the bOPV was added to the national immunization program at ages 6 and 18 months during the study period, and parents were required to specifically report rotavirus immunization, rather than oral immunization in general.

In summary, we demonstrated high sensitivity of parental reports of their child's vaccination with a rotavirus vaccine in comparison to the national immunization registry; however, the specificity was relatively low. The child's age affected the accuracy of

parental reports of immunization status. Vaccine effectiveness was similar regardless of the classification method of rotavirus immunization status; therefore, parental reporting on vaccination status is a useful tool in vaccine effectiveness assessment.

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### Conflict of interest

None.

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### Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.vaccine.2019.04.037>.

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