

Update of RotaTeq® Vaccine Reports to VAERS, 3/1/06-9/25/07

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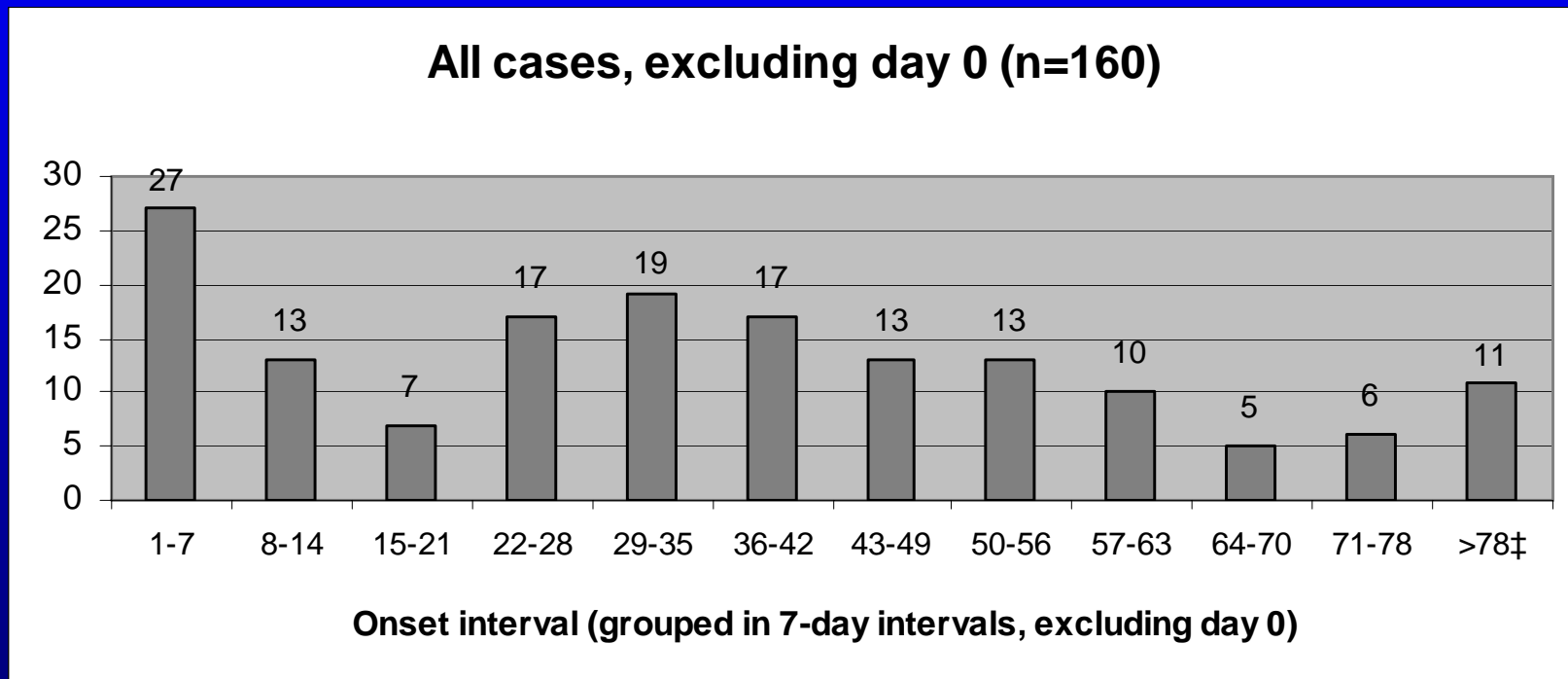
VAERS Intussusception (IS) Reports* after RotaTeq[®] Vaccine

- **9.1 million doses distributed (March 2006- August 31, 2007)***
- **160 confirmed Intussusception (IS) reports**
 - **47 reports 1-21 days after vaccination**
 - **27 of 47 were within 1-7 days**



* Based on Brighton case definition –level 1

RotaTeq[®] IS Reports to VAERS by Onset-Interval (N=160)*



*excludes two reports on day zero

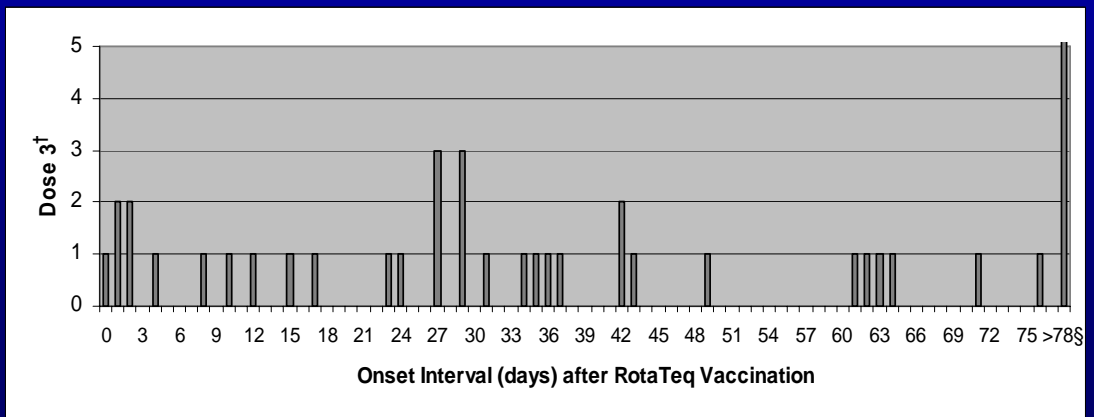
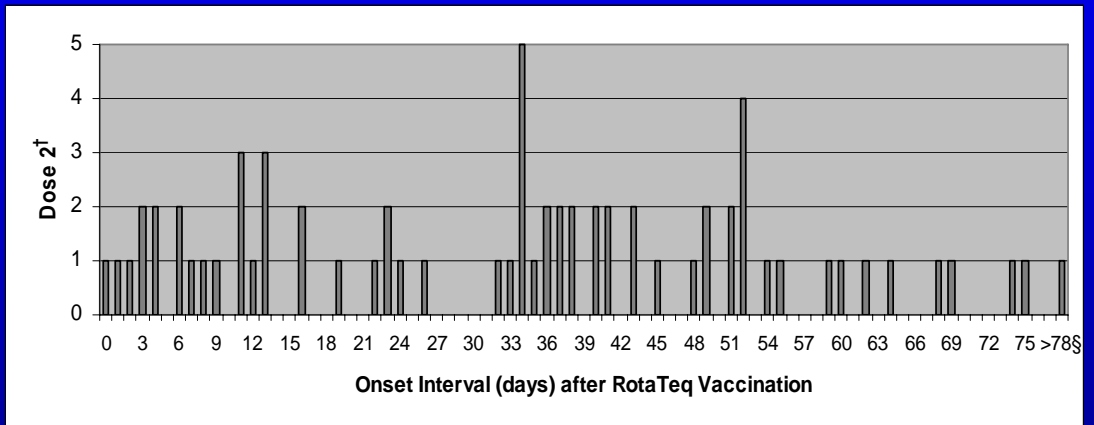
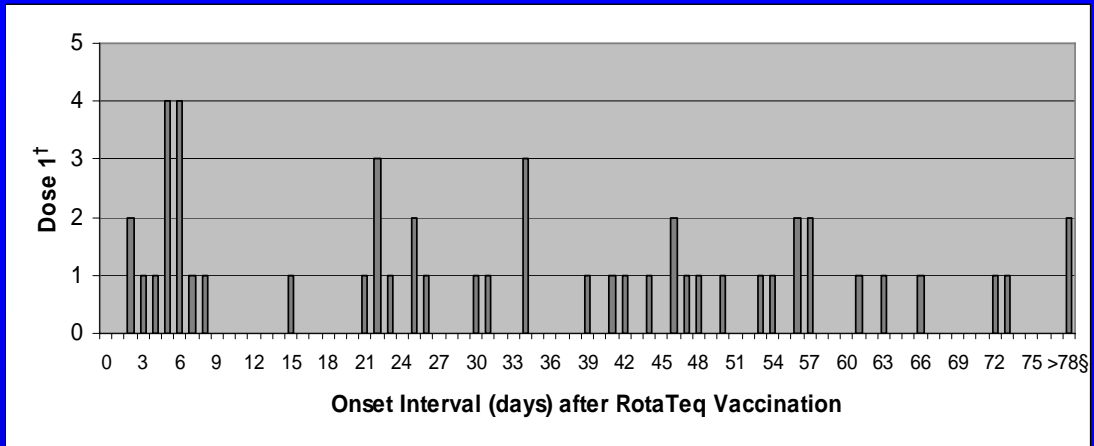


IS Reports by Dose

N=50

N=68

N=42



Observed versus expected calculations

- Age-stratified analysis important since baseline intussusception rate varies 10-fold during 1st six months of life
- 3 doses of vaccine are administered during this time period
- Data assumptions
 - Reporting completeness to VAERS
 - Number of vaccine doses administered



Observed versus Expected 1 to 21 Days* (any dose)

Age Group	VAERS Cases	Expected Cases*
6-14	16	40
15-23	19	55
24-35	12	56
Total	47	151

Exact Poisson—Stratified by age group

Rate Ratio	Lower 95% CL	Upper 95% CL	P-Value
0.30	0.20	0.44	<0.001

Data assumptions:

- 100% VAERS reporting completeness
- 100% distributed doses administered



* Source: VSD for background and age of vaccine administration; Merck distribution data

Observed versus Expected 1 to 7 Days* (any dose)

Age Group	VAERS Cases	Expected Cases*
6-14	12	13
15-23	10	18
24-35	5	19
Total	27	50

Exact Poisson—Stratified by age group

Rate Ratio	Lower 95% CL	Upper 95% CL	P-Value
0.51	0.32	0.81	0.002

Data assumptions:

- 100% VAERS reporting completeness
- 100% distributed doses administered



* Source: VSD for background and age of vaccine administration; Merck distribution data

Sensitivity Analysis*

ASSUMPTIONS

75% reporting to VAERS

75% of distributed doses are administered

	VAERS Cases	Expected Cases*	RR (95% CL)
1 – 21 days	62	113	0.53 (0.37 – 0.75)
1 – 7 days	36	38	0.91 (0.59– 1.37)

ASSUMPTIONS

50% reporting to VAERS

50% of distributed doses are administered

	VAERS Cases	Expected Cases*	RR (95% CL)
1 – 21 days	94	76	1.18 (0.87 – 1.62)
1 – 7 days	54	25	2.01 (1.39– 2.89)

* Source: VSD for background and age of vaccine administration; Merck distribution data

RotaTeq[®] IS Data from Vaccine Safety Datalink (VSD)

- From May 21, 2006 through Oct 6, 2007:
- Total of 111,521 vaccinations given
 - 3 cases of IS were identified based on ICD9 code within 30 days of vaccination
 - Chart review to confirm the cases is currently underway
 - 1 case after dose 1; onset 20 days
 - 2 cases after dose 2; onset 17 and 10 days
 - 3.4 reports of intussusception expected by chance alone*

* VSD Rapid cycle analysis (RCA) background rates



Update on VSD Rapid Cycle Analysis*

(Oct. 6, 2007)

Age Group	Dose 1	Dose 2	Dose 3	Total
0-6 Weeks	37	1	0	38
6-14 Weeks	46,652	258	4	46,914
15-23 Weeks	2,043	33,893	84	36,020
24-35 Weeks	961	2,643	24,452	28,056
36-52 Weeks	62	54	210	326
NA	147	11	9	167
Total	49,902	36,860	24,759	111,521

*Data from 6 sites; 45%; 33%; 22%



Conclusion and Next Steps

- Observed intussusception rates following RotaTeq[®] are not greater than expected
 - interpreted with limitations of passive surveillance
- VSD data after > 100,000 vaccinations show no evidence of increased risk
- Continue to follow VSD and Merck post-licensure cohorts



Thank you

