

Supplemental Material to:

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Reactogenicity and safety of a liquid human rotavirus vaccine (RIX4414) in healthy adults, children and infants in China: Randomized, double-blind, placebo-controlled Phase I studies

2013; 9(8) http://dx.doi.org/10.4161/hv.25076

www.landesbioscience.com/journals/vaccines/article/25076

Table S1. Percentage of children reporting each solicited AE during the 8-day follow-up period (day 0–7) after vaccination (all and grade 3 intensity) (ROTA-073 pediatric study; TVC)

	Human RV vaccine (N = 25)		Placebo (N = 25)	
	n (%)	95% CI	n (%)	95% CI
Cough				
All	10 (40)	21.1, 61.3	12 (48)	27.8, 68.7
Grade 3	0 (0)	0.0, 13.7	0 (0)	0.0, 13.7
Diarrhea				
All	1 (4)	0.1, 20.4	1 (4)	0.1, 20.4
Grade 3	0 (0)	0.0, 13.7	1 (4)	0.1, 20.4
Irritability				
All	3 (12)	2.5, 31.2	2(8)	1.0, 26.0
Grade 3	0 (0)	0.0, 13.7	0 (0)	0.0, 13.7
Loss of appetite				
All	2 (8)	1.0, 26.0	3 (12)	2.5, 31.2
Grade 3	0 (0)	0.0, 13.7	0 (0)	0.0, 13.7
Fever (WHO scale)				
All (≥37.5°C)	4 (16)	4.5, 36.1	5 (20)	6.8, 40.7
Grade 3 (≥39.0°C)	0 (0)	0.0, 13.7	0(0)	0.0, 13.7
Fever (Chinese scale)				
All (≥37.1°C)	1 (4)	0.1, 20.4	2 (8)	1.0, 26.0
Grade 3 (≥39.0°C)	0 (0)	0.0, 13.7	0 (0)	0.0, 13.7
Vomiting				
All	1 (4)	0.1, 20.4	0 (0)	0.0, 13.7
Grade 3	0 (0)	0.0, 13.7	0 (0)	0.0, 13.7

Grade 3 AEs defined as cough which prevented normal daily activity, ≥ 6 looser than normal stools per day, crying that could not be comforted or which prevented normal daily activity, not eating at all, and ≥ 3 episodes of vomiting/day

^{95%} CI, 95% confidence interval