

Supplemental Material to:

Stephen Rinderknecht, Kristina Bryant, Terry Nolan, Noris Pavia-Ruz, Carlos Aranza Doniz, Miguel Angel Rodriguez Weber, Christopher Cohen, Emmanuel Aris, Narcisa Mesaros and Jacqueline M Miller. The safety profile of *Haemophilus influenzae* type b-*Neisseria meningitidis* serogroups C and Y tetanus toxoid conjugate vaccine (HibMenCY). *Human Vaccines & Immunotherapeutics* 2012; 8(3); <http://dx.doi.org/10.4161/hv.8.3.18752>
<http://www.landesbioscience.com/journals/vaccines/article/18752>

Supplementary Table: Relative risk of serious adverse events (with an incidence of at least 0.1% but <0.3% in either group), reported from Dose 1 until 6 months post-dose 4 (Total vaccinated cohort, all studies)

Symptom (Preferred term)	HibMenCY	Hib	Relative Risk	p-value
	N=6414	N=2157		
	n (%)	n (%)	[95% CI]	
At least one	388 (6.0)	130 (6.0)	1.00 [0.82; 1.23]	1.00
Intussusception	4 (0.1)	3 (0.1)	0.45 [0.08; 3.05]	0.49
Vomiting	3 (0.0)	3 (0.1)	0.34 [0.05; 2.53]	0.35
Pyrexia	7 (0.1)	3 (0.1)	0.79 [0.18; 4.74]	0.97
Sudden infant death syndrome	4 (0.1)	2 (0.1)	0.67 [0.10; 7.42]	0.94
Cellulitis	4 (0.1)	1 (0.0)	1.35 [0.13; 66.38]	1.00
Croup infectious	8 (0.1)	4 (0.2)	0.68 [0.18; 3.07]	0.72
Gastroenteritis rotavirus	11 (0.2)	3 (0.1)	1.24 [0.33; 6.95]	1.00
Gastroenteritis viral	2 (0.0)	2 (0.1)	0.34 [0.02; 4.68]	0.53
Influenza	2 (0.0)	2 (0.1)	0.34 [0.02; 4.68]	0.53
Otitis media	11 (0.2)	5 (0.2)	0.74 [0.24; 2.73]	0.76
Pharyngitis	2 (0.0)	2 (0.1)	0.33 [0.02; 4.60]	0.52
Pyelonephritis	4 (0.1)	1 (0.0)	1.35 [0.13; 66.61]	1.00
Respiratory syncytial virus infection	7 (0.1)	4 (0.2)	0.59 [0.15; 2.77]	0.59
Staphylococcal infection	5 (0.1)	0 (0.0)	INF [0.31; INF]	0.46
Tracheitis	1 (0.0)	3 (0.1)	0.11 [0.00; 1.39]	0.10
Upper respiratory tract infection	7 (0.1)	1 (0.0)	2.37 [0.30; 106.83]	0.72
Urinary tract infection	13 (0.2)	1 (0.0)	4.39 [0.66; 186.76]	0.19
Viral infection	16 (0.2)	3 (0.1)	1.79 [0.51; 9.61]	0.51
Viral upper respiratory tract infection	2 (0.0)	2 (0.1)	0.34 [0.02; 4.68]	0.53
Head injury	12 (0.2)	4 (0.2)	1.00 [0.30; 4.26]	1.00
Convulsion	5 (0.1)	2 (0.1)	0.84 [0.14; 8.84]	1.00

Febrile convulsion	14 (0.2)	5 (0.2)	0.94 [0.32; 3.33]	1.00
Asthma	10 (0.2)	3 (0.1)	1.13 [0.29; 6.37]	1.00
Bronchial hyperreactivity	10 (0.2)	3 (0.1)	1.12 [0.29; 6.35]	1.00
Hypoxia	6 (0.1)	1 (0.0)	2.04 [0.25; 93.65]	0.87
Respiratory distress	8 (0.1)	1 (0.0)	2.71 [0.36; 120.45]	0.58

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term); N = number of subjects with at least one administered dose; n (%) = number (percentage) of subjects reporting the symptom at least once; 95% CI = 95% confidence interval for relative risk (Exact Stratified Conditional to total number of cases); P-Value = 2-sided Exact Stratified Test conditional to number of cases. INF = infinity.