Table 4. Serious adverse events and medically-attended adverse events up to Day 56

SOC/PT	IXIARO 0.25 mL 2 vaccinations	IXIARO 0.5 mL 2 vaccinations	Prevnar 2-3 vaccinations	HAVRIX 720 1 vaccination	p-value
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	
AGE GROUP ≥2 MONTHS TO <1 YEAR					
N	131		64		
SAEs					
Nervous system disorders	0 [0.0, 2.8]		1 (1.6) [0.0, 8.4]		0.328
Febrile convulsions	0 [0.0, 2.8]		1 (1.6) [0.0, 8.4]		0.328
Medically-attended AEs with an incidence of ≥3% in at least 1 group					
Infections and infestations	47 (35.9) [27.7, 44.7]		23 (35.9) [24.3, 48.9]		1.000
Upper respiratory tract infection	20 (15.3) [9.6, 22.6]		15 (23.4) [13.8, 35.7]		0.170
Gastroenteritis	9 (6.9) [3.2, 12.6]		0 [0.0, 5.6]		0.032
Impetigo	4 (3.1) [0.8, 7.6]		2 (3.1) [0.4, 10.8]		1.000
Furuncle	3 (2.3) [0.5, 6.5]		2 (3.1) [0.4, 10.8]		0.664

General disorders and administration site conditions	5 (3.8) [1.3, 8.7]		2 (3.1) [0.4, 10.8]		1.000
Pyrexia	5 (3.8) [1.3, 8.7]		1 (1.6) [0.0, 8.4]		0.666
AGE GROUP ≥1 YEAR TO <3 YEARS					
N	640			213	
SAEs					
Infections and infestations	4 (0.6) [0.2, 1.6]			1 (0.5) [0.0, 2.6]	1.000
Gastroenteritis	1 (0.2) [0.0, 0.9]			1 (0.5) [0.0, 2.6]	0.437
Bronchopneumonia	1 (0.2) [0.0, 0.9]			0 [0.0, 1.7]	1.000
Cellulitis	1 (0.2) [0.0, 0.9]			0 [0.0, 1.7]	1.000
Dengue fever	1 (0.2) [0.0, 0.9]			0 [0.0, 1.7]	1.000
Nervous system disorders	2 (0.3) [0.0, 1.1]			2 (0.9) [(0.1, 3.4]	0.261
Febrile convulsion	2 (0.3) [0.0, 1.1]			2 (0.9) [(0.1, 3.4]	0.261
Respiratory, thoracic and mediastinal disorders	0 [0.0, 0.6]			1 (0.5) [0.0, 2.6]	0.250
Dyspnoea	0 [0.0, 0.6]			1 (0.5) [0.0, 2.6]	0.250

Vascular disorders	1 (0.2) [0.0, 0.9]			0 [0.0, 1.7]	1.000
Haematoma	1 (0.2) [0.0, 0.9]			0 [0.0, 1.7]	1.000
Medically-attended AEs with an incidence of ≥3% in at least 1 group					
Infections and infestations	146 (22.8) [19.6, 26.3]			39 (18.3) [13.4, 24.2]	0.180
Upper respiratory tract infection	61 (9.5) [7.4, 12.1]			17 (8.0) [4.7, 12.5]	0.584
Gastroenteritis	19 (3.0) [1.8, 4.6]			6 (2.8) [1.0, 6.0]	1.000
AGE GROUP ≥3 YEARS TO <12 YEARS[1]					
N	100	300		101	
No SAEs occurred to Day 56. No Medically attended AE was reported by ≥3% of subjects.					
AGE GROUP ≥12 YEARS TO <18 YEARS[1]					
N		240		80	
No SAEs occurred to Day 56. No Medically attended AE was reported by ≥3% of subjects.					

p-value is from a Fisher's exact test comparing the number of subjects with the event across the treatment groups.

Percentages are based on the number of subjects in the treatment group in a given age group. The confidence interval is an exact confidence interval for a percentage.

AE, adverse event; CI, confidence interval; n, number of subjects who experienced each event; N, number of subjects in the Safety Population in the indicated vaccine and age group; NC, Not calculable, insufficient observations to perform a Fisher's exact test; PT, MedDRA preferred term; SAE, serious adverse event; SOC, MedDRA system organ class.