THE LANCET Infectious Diseases

Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Estívariz CF, Anand A, Gary Jr HE, et al. Immunogenicity of three doses of bivalent, trivalent, or type 1 monovalent oral poliovirus vaccines with a 2 week interval between doses in Bangladesh: an open-label, non-inferiority, randomised, controlled trial. *Lancet Infect Dis* 2015; published online June 18. http://dx.doi.org/10.1016/S1473-3099(15)00094-8.

Appendix text

Logistic regression analysis: Methodology and results

Based upon previous studies on factors that interfere with the immunogenicity of oral polio vaccine,[1,22,23] the following epidemiological and clinical variables were assessed to determine influence on failure to seroconvert to type 1 and type 3 poliovirus: gender, residence in Matlab or Mirpur, mother's education below 5 years, moderate to severe stunting or wasting detected in at least one visit, full breast feeding during all three follow- up visits, breast- feeding 15 minutes or less before receiving any OPV dose, receiving a dose of Rotarix vaccine concomitantly with an OPV dose, high maternal antibodies at baseline (≥1/72), and receiving at least 2 OPV doses during the rainy season. Although diarrhea at the time of OPV administration is known to interfere with the immune response, we did not include this variable because only three children presented with diarrhea during a study visit.

Univariate analysis found potential interference of some risk factors on seroconversion to type 1 poliovirus, only after administration of the tOPV series (Table 1 of appendix); not after administration of the mOPV1 or bOPV series (results not shown). For type 3 poliovirus, univariate analysis found influence of some risk factors on seroconversion after the bOPV series administered with the standard schedule and after the tOPV series (Table 1 of appendix). All variables assessed in univariate analysis were included in logistic regression analysis. The results presented are adjusted odds ratio and 95% confidence intervals. Logistic regression analysis including only variables with a significance value of $P<0.2$ in univariate analysis was also conducted, and provided similar results (data not shown).

No technique for imputing missing values was used because of the small number observed. Only 7.3% of enrolled participants had missing outcome data; of these, 3.8% had no or insufficient sample and could be considered missing completely at random, and only 3.5%, were refusals who may have been missing because of factors that could be related to the outcome.

Appendix Table 1. Proportion of infants who seroconvert to type 1 or type 3 poliovirus by several risk factors.

		Type 1 poliovirus			Type 3 poliovirus					
		E. tOPV standard schedule			B. bOPV standard schedule			E. tOPV standard schedule		
Factor		**N**	**SC**	**P value**	**N**	**SC**	**P value**	**N**	**SC**	**P value***
Gender	Female	89	90%	0·3	98	96%	1·0	89	84%	0·2
	Male	101	94%		86	95%		101	91%	
Setting	Mirpur	79	87%	0·04	80	91%	0·02	79	80%	0·004
	Matlab	111	96%		104	99%		111	94%	
Mother's education	>5 years	88	94%	0·3	81	98%	0·5	88	88%	0·9
	<5 years	102	90%		103	94%		102	88%	
Stunting moderate-severe in any visit	No	142	95%	0·009	137	99%	0·004	142	90%	0·1
	Yes	48	83%		47	87%		48	81%	
Wasting moderate-severe in any visit	No	139	92%	1·0	133	95%	0·4	139	87%	0·6
	Yes	51	92%		51	98%		51	90%	
Full breast feeding in all visits	No	26	73%	0·0001	22	86%	0.06	26	81%	0·3
	Yes	164	95%		162	97%		164	89%	
Received Rotarix same day as OPV	No	157	92%	1·0	147	95%	1·0	157	86%	0·1
	Yes	33	94%		37	97%		33	97%	
Breast feeding <15 minutes before OPV	No	148	92%	1·0	143	94%	0·2	148	87%	0·8
	Yes	42	93%		41	100%		42	90%	
High maternal antibodies (≥1:72)	No	170	94%	0·02	167	96%	0·5	170	92%	<·0001
	Yes	20	81%		17	94%		20	55%	
Received ≥ two doses during rainy months	No	105	92%	0·9	105	95%	1·0	105	83%	0·02
	Yes	85	92%		79	96%		85	94%	

SC = Seroconversion. * For chi square or Fisher's exact test.

Appendix Table 2. Distribution of the diagnosis of reported adverse events by study group.

Diagnosis	A. bOPV short schedule	B. bOPV standard schedule	C.mOPV1 short schedule	D.mOPV1 standard schedule	E. tOPV standard schedule	Total
Serious Adverse Events						
Pneumonia	5	8*	8	6	5	**30**
Vomiting	1	0	0	0	0	**1**
Diarrhea with severe malnutrition	0	0	0	0	1	**1**
Feeding problem	0	0	0	1	0	**1**
Septicaemia	1	0	0	0	0	**1**
Total	**7**	**8**	**8**	**7**	**6**	**36**
Mild-Moderate Adverse Events						
Acute respiratory infection	12	8	7	7	10	**44**
Diarrhea	3	2	0	2	3	**10**
Fever without infectious focus	1	1	1	2	2	**7**
Conjunctivitis	1	0	0	0	0	**1**
Viral fever	0	0	1	1	0	**2**
Pain with urination	1	0	0	0	0	**1**
Feeding problem	0	0	1	0	0	**1**
Pneumonia	0	0	0	0	1	**1**
Rash	0	0	1	0	0	**1**
Total	**18**	**11**	**11**	**12**	**16**	**68**

*One child had the diagnosis of pneumonia with severe malnutrition and another one had pneumonia with diarrhea and severe malnutrition.