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Supplementary appendix

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Supplementary appendix

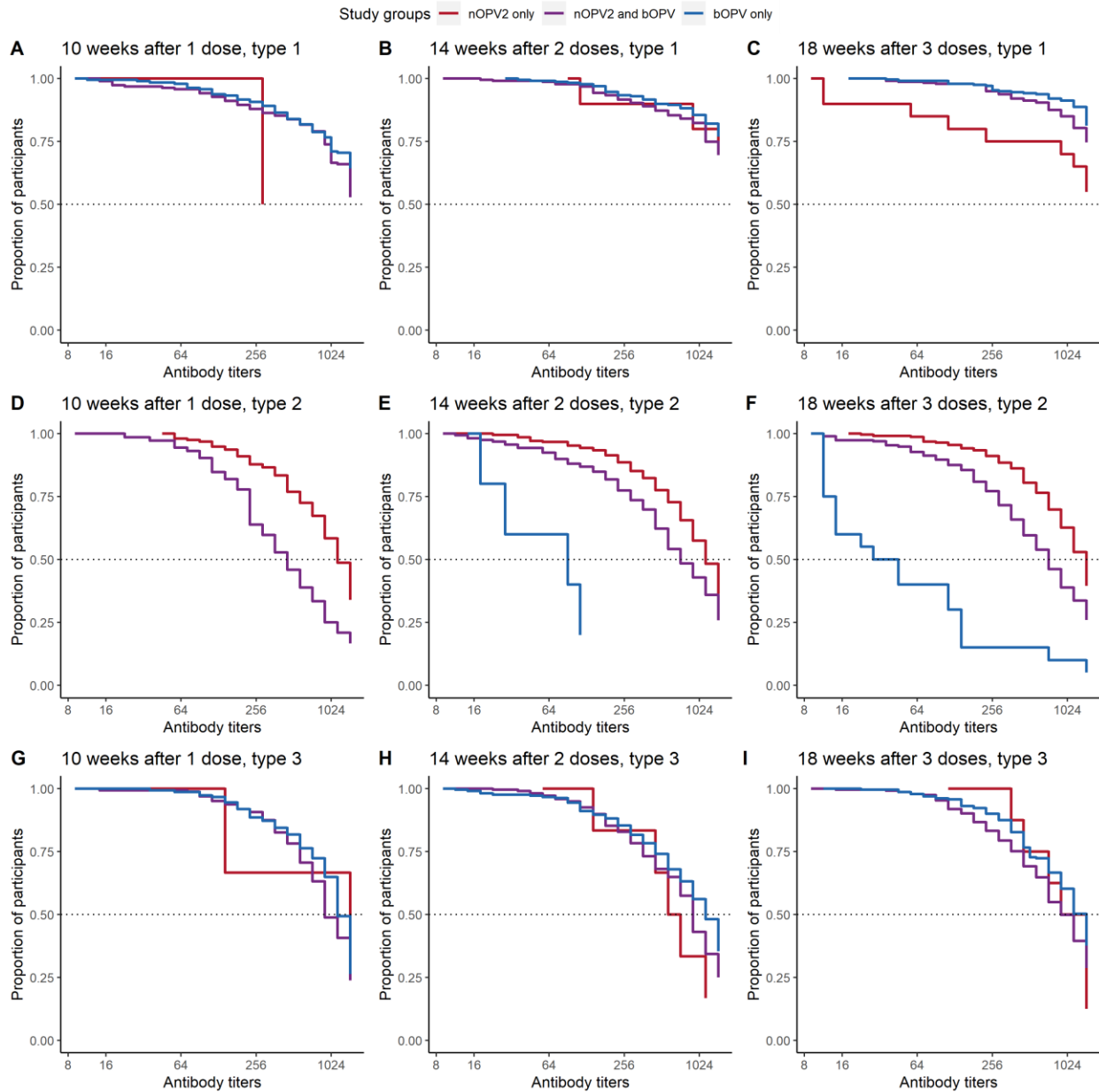
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Supplementary Table 1: Reciprocal neutralizing antibody titers for poliovirus types 1, 2, and 3 among immune responders, by study group, intention-to-treat population

	Group A (nOPV2 only [n=244])	Group B (nOPV2 and bOPV [n=246])	Group C (bOPV only [n=246])	Kruskal-Wallis test
Poliovirus type 1				
Antibody titres at 10 weeks after 1 dose	2; 151 (83 to 220)	191; ≥1448 (724 to ≥1448)	193; ≥1448 (910 to ≥1448)	B vs C: p=0.076
Antibody titres at 14 weeks after 2 doses	10; ≥1448 (1045 to ≥1448)	227; ≥1448 (1031 to ≥1448)	229; ≥1448 (≥1448 to ≥1448)	B vs C: p=0.079
Antibody titres at 18 weeks after 3 doses	20; ≥1448 (199 to ≥1448)	240; ≥1448 (1152 to ≥1448)	240; ≥1448 (≥1448 to ≥1448)	B vs C: p=0.057
Poliovirus type 2				
Antibody titres at 10 weeks after 1 dose	156; 910 (455 to ≥1448)	72; 362 (181 to 771)	NA	A vs B: p<0.0001
Antibody titres at 14 weeks after 2 doses	209; 910 (455 to ≥1448)	159; 576 (228 to ≥1448)	5; 28 (18 to 91)	A vs B: p=0.0007
Antibody titres at 18 weeks after 3 doses	225; 1152 (576 to ≥1448)	193; 576 (228 to ≥1448)	20; 26 (11 to 114)	A vs B: p<0.0001
Poliovirus type 3				
Antibody titres at 10 weeks after 1 dose	3; 144 (79 to 796)	160; 724 (455 to 1152)	148; 910 (576 to ≥1448)	B vs C: p=0.11
Antibody titres at 14 weeks after 2 doses	6; 516 (222 to 687)	216; 724 (288 to 1226)	212; 910 (362 to ≥1448)	B vs C: p=0.026
Antibody titres at 18 weeks after 3 doses	8; 817 (432 to 910)	233; 817 (362 to ≥1448)	231; 1152 (455 to ≥1448)	B vs C: p=0.0092

Data are the number of vaccine responders (n) and the median (IQR) of reciprocal antibody titers among vaccine responders. P values are reported for comparisons of interest (i.e., they include comparisons between study vaccines without a specific serotype). nOPV2 = novel oral poliovirus vaccine type 2; bOPV = bivalent oral poliovirus; NA = not applicable, no vaccine responders.

Supplementary Figure 1: Reverse cumulative distribution curves of reciprocal neutralizing antibody titres to poliovirus types 1, 2, and 3 by study group and time, intention-to-treat population. (A–I) Proportion of participants (y-axis) with measured reciprocal neutralizing antibody and greater (x-axis) among immune responders at 10, 14, and 18 weeks of age by poliovirus type. nOPV2 = novel oral poliovirus vaccine type 2; bOPV = bivalent oral poliovirus.



Supplementary Table 2: Immune response for poliovirus types 1, 2, and 3 by study group, per-protocol population

	Group A (nOPV2 only [n=230])	Group B (nOPV2 and bOPV [n=225])	Group C (bOPV only [n=231])
Poliovirus type 1			
Immune response at 10 weeks after 1 dose	2 (1%, 0-3)	173 (77%, 71-82)	183 (79%, 74-84)
Cumulative immune response by 14 weeks after 2 doses	10 (4%, 2-8)	208 (92%, 88-95)	215 (93%, 89-96)
Cumulative immune response by 18 weeks after 3 doses	20 (9%, 6-13)	220 (98%, 95-99)	225 (97%, 94-99)
Poliovirus type 2			
Immune response at 10 weeks after 1 dose	147 (64%, 58-70)	66 (29%, 24-36)	0 (0%, 0-2)
Cumulative immune response by 14 weeks after 2 doses	196 (85%, 80-89)	148 (66%, 59-72)	4 (2%, 1-4)
Cumulative immune response by 18 weeks after 3 doses	211 (92%, 87-95)	179 (80%, 74-84)	17 (7%, 5-11)
Poliovirus type 3			
Immune response at 10 weeks after 1 dose	3 (1%, 0-4)	144 (64%, 58-70)	140 (61%, 54-67)
Cumulative immune response by 14 weeks after 2 doses	6 (3%, 1-6)	196 (87%, 82-91)	200 (87%, 82-90)
Cumulative immune response by 18 weeks after 3 doses	8 (3%, 2-7)	213 (95%, 91-97)	218 (94%, 91-97)

Data are the number of vaccine responders (% , 95% CI). nOPV2 = novel oral poliovirus vaccine type 2; bOPV = bivalent oral poliovirus vaccine.

Supplementary Figure 2: Non-inferiority assessment of immune response to poliovirus types 1, 2, and 3, per-protocol population

Differences in vaccine response are presented along with 90% CIs around the estimated difference. Dashed line represents the non-inferiority margin, defined as -10%. Non-inferiority is concluded if the lower bound of the 90% CI falls to the right of the non-inferiority margin. (A) Type 1, nOPV2 and bOPV (Group B) in comparison with bOPV only (Group C), (B) Type 2, nOPV2 and bOPV (Group B) in comparison with nOPV2 only (Group A), (C) Type 3, nOPV2 and bOPV (Group B) in comparison with bOPV only (Group C). nOPV2 = novel oral poliovirus vaccine type 2; bOPV = bivalent oral poliovirus.

