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An observational, cohort, multi-centre, open label phase IV extension study comparing IPV immune responses to preschool dTaP-IPV booster vaccines in children whose mothers received or did not receive an IPV-containing pertussis vaccine during pregnancy in England

Kajal Radia [a,*,1], Shari Sapuan [a,2], Nicholas Grassly [b], Nick Andrews [c], Mary Ramsay [c], Vanessa Saliba [c], Laura Stephens [d], Javier Martin [d], Christine Jones [e], Elizabeth Miller [f], Paul T. Heath [a]

[a] Vaccine Institute, City St George's, University of London, Cranmer Terrace, London SW17 0RE, United Kingdom
[b] Imperial College London School of Public Health, 1102 Sir Michael Uren Hub, White City Campus, W12 0BZ, United Kingdom
[c] UK Health Security Agency (UKHSA), 61 Colindale Avenue, London NW9 5EQ, United Kingdom
[d] Medicines and Healthcare Products Regulatory Agency, Blanche Lane, South Mimms, Potters Bar, Hertfordshire EN6 3QG, United Kingdom
[e] Faculty of Medicine and Institute for Life Sciences, University of Southampton and NIHR Southampton Clinical Research Facility and NIHR Southampton Biomedical Research Centre, University Hospital Southampton NHS Foundation Trust, Tremona Road, Southampton SO16 6YD, United Kingdom
[f] Department of Infectious Disease Epidemiology LSHTM, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT, United Kingdom

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ABSTRACT

A diphtheria-tetanus-acellular pertussis-inactivated polio combination vaccine (dTaP-IPV) was offered as part of the UK antenatal vaccination programme from 2012 to July 2024. Prior research established that infants of mothers who received a dTaP-IPV vaccine in pregnancy have significantly reduced poliovirus-specific neutralising antibodies after their primary immunisation series compared with infants of non-dTaP-IPV vaccinated mothers. We investigated whether sufficient poliovirus-specific neutralising antibody titres are achieved in these children following the pre-school dTaP-IPV booster vaccine. Poliovirus-specific neutralising antibody titres were measured, via a microneutralisation assay, prior to and following receipt of the pre-school booster vaccine in blood samples taken during an observational, cohort, multi-centre, open label phase IV extension study.

Prior to the pre-school boost, children of mothers who received dTaP-IPV vaccines in pregnancy had lower geometric mean titres (GMT) of antibodies than children of unvaccinated mothers (4.3 vs 54.7, $p = 0.0001$). However, following administration of the pre-school booster all children, regardless of maternal vaccination status achieved protective antibody titres (≥ 8), although children of vaccinated mothers still had lower GMTs (988 vs 2964, $p = 0.009$).

Administration of the preschool booster overcomes the polio virus immunity gap that develops following the primary vaccination series in children whose mothers received an antenatal dTaP-IPV vaccine versus unvaccinated mothers. Residual differences in post-booster titres warrant continued surveillance to assess their clinical relevance. Clinical trials registry:NCT03578120

1. Introduction

The UK antenatal pertussis vaccination programme used a diphtheria-tetanus-acellular pertussis-inactivated polio combination vaccine (dTaP-IPV) from 2012 until June 2024. Maternal immunisation substantially reduces the risk of severe pertussis infection in infants in the first few months of life [1]. However, there is now clear evidence that high levels of maternally derived antibodies can modulate the

* Corresponding author.
E-mail address: kajal.radia1@nhs.net (K. Radia).
[1] Imperial College Healthcare NHS Trust, The Bays, S Wharf Rd, London W2 1NY, United Kingdom.
[2] St George's University Hospitals NHS Foundation Trust. Paediatrics, Blackshaw Rd, London SW17 0QT, United Kingdom.

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antibody response of infants following the primary series to both pertussis [2–4]and polio [5,6] (also termed 'blunting' [7]). No clinical impact of this has been shown for pertussis in the first years of life. Reduced immune responses to poliovirus may, however, be clinically relevant as it could expose young children to the risk of polio [8] in the context of circulating vaccine derived poliovirus type 2 (VDPV2). VDPV2 was detected in London sewage samples between February and November 2022 [9]. Circulating VDPV2 is an urgent reminder that suboptimal immunity to poliovirus could have clinical implications and highlights the threat that vaccine-derived viruses present to the global polio eradication initiative launched by the WHO in 1988.

In July 2024 the programme switched to using dTaP without IPV following advice from the Joint Committee on Vaccination and Immunisation (JCVI) [10]. The prior inclusion of IPV in the antenatal vaccine and UK childhood immunisation schedule for polio comprising a primary series given at 2, 3 and 4 months and a preschool booster at 3 years 4 months set the UK apart from other countries' vaccination programmes [5,11]. The long-term effects of these differences have not been investigated in the UK. It is unclear whether the immunity gap observed post-primary series [5] persists until the preschool booster and whether the immunity gap is overcome by the administration of the later (preschool) booster as given in the UK schedule. If the immunity gap is maintained until the preschool booster dose, this indicates a potential vulnerability to poliovirus infections in children aged 1–3 years old. Moreover, if sufficient poliovirus protection is not attained after administration of the preschool booster there may be a risk to the whole population from VDPV2 circulation [12].

In order to determine whether the reduced poliovirus antibody responses observed at 13 months persist up to administration of the preschool booster and whether the preschool booster restores protective immunity, we measured poliovirus-specific neutralising antibodies in samples collected from children as part of the iMAP3 study [4]. Samples were collected at preschool age (post-primary series and prior to the preschool booster vaccination) and again following the booster vaccination.

2. Methods

2.1. Study design

The design of this observational, multi-centre, open label phase IV extension study has been described previously [4]. Briefly, children at preschool age, due for their preschool booster and who had taken part in the iMAP2 study, were invited to participate in iMAP3. The iMAP2 study was a phase 4 multi-centre randomised trial comparing the effect of two different dTaP-IPV vaccinations (Repevax; Sanofi Pasteur, or Boostrix-IPV; GlaxoSmithKline) given in pregnancy, with a non-randomised control group, on infant antibody concentrations (initially pertussis specific antibodies [2] and later poliovirus specific neutralising antibodies [5]) up to 13 months of age. Of the 144 children participating in the iMAP2 study, 63 were recruited between March 2018 and September 2019 for the iMAP3 study. Exclusion criteria included the presence of any of the contraindications to vaccination specified in the Greenbook [13], or receipt of an additional pertussis-containing vaccine outside of the usual schedule.

In the iMAP3 study, two venous blood samples were taken via venepuncture, following written, informed parental consent. The first sample was taken prior to the receipt of the preschool booster and the second 28–35 days after the preschool booster. The preschool booster comprised Repevax (dTaP5-IPV; Sanofi Pasteur) and was given at 3 years 4 months of age as per the UK immunisation schedule.

The study was approved by the NHS Health Research Authority and the London Brent Research Ethics Committee (18/NW/0095), clinical trials registration number NCT03578120.

2.2. Outcomes

The primary outcome was the difference in poliovirus serum neutralising antibody titres post receipt of the preschool booster, between children born to mothers who received one of two DTaP-IPV antenatal vaccines (Boostrix-IPV or Repevax), compared with those who did not. As well as the geometric mean titres (GMTs), the proportion with titres $\geq$ 4, the lower limit of detection, and with protective titres ($\geq$ 8) [14–16] are presented. Secondary outcomes included the differences in serum neutralising antibody titres against poliovirus in these groups of children prior to receipt of the preschool booster.

2.3. Poliovirus specific neutralising antibodies

Poliovirus serum neutralising antibodies to type 2 poliovirus were measured at the UK Medicines and Healthcare Regulatory Agency (MHRA) following the WHO protocol with the S19-Sabin 2 poliovirus hyper-attenuated strain as the challenge [17]. The International Reference for anti-poliovirus serum (82/585) was used as a working reference and tested in parallel to confirm the validity and sensitivity of the tests. Due to limited volumes of sera available for testing, seroresponses to type 2 poliovirus only was tested. This was chosen as it was the most relevant in the context of VDPV2 circulation detected in environmental surveillance [18]. Limited serum per participant meant some sera required dilution, so the lower limit of detection for the assay was $\geq$ 4. Laboratory staff were blinded to the study arm.

2.4. Statistical analysis

Data were stratified into the three different groups: children born to mothers who received Repevax, Boostrix-IPV, and no IPV containing vaccine in pregnancy. GMTs were calculated with 95% confidence intervals and comparisons of titres between groups done using the non-parametric Kruskal Wallis test. Normality of logged titres was assessed visually in histograms. As some were skewed, formal testing was done with a non-parametric test, but geometric means were still calculated with 95% confidence intervals. Even for skewed data, 95% confidence intervals are appropriate for the mean as the central limit theorem leads to approximately normal distributions unless sample sizes are very small. Where sample sizes are <20 a footnote has been added to indicate that the 95% CIs are approximate due to small numbers and skewed data.

Proportions above threshold values were compared via Fisher's exact test and by logistic regression adjusted for gender and time since vaccination. To maximise the power of the study the two vaccinated study arms, after confirming no significant differences, were combined for comparison with the arm with no maternal vaccinations. It was assumed missing data were missing at random and excluded from analysis and children who had either a pre-boost or post-boost Polio 2 result were included in analysis.

The GMTs over time were also plotted on a log-titre by timepoint graph.

Analyses were conducted using stata version 17 (STATACORP, TX, USA).

3. Results

Of the children recruited for the iMAP3 study, 61 had poliovirus neutralising antibody results available, obtained either prior to, and/or post receipt of the preschool booster (24 Boostrix-IPV, 22 Repevax, and 15 born to unvaccinated mothers). Details of those recruited have been published previously [4]. No statistically significant differences were observed in demographic factors between those recruited and those not recruited from the iMAP2 study.

Table 1
Geometric mean titres (GMTs) of poliovirus neutralising antibody post primary immunisations at 5 months and 13 months of age in children born to mothers given Boostrix-IPV, Repevax or no DTaP-IPV in pregnancy.

Age	Group	N	GMT (95% CI)	*P*-value*
5 months	**Boostrix-IPV**	23	30.0 (19.1–47.1)	0.33
	Repevax	19	44.1 (24.9–78.2)**	
	Either Vaccine	42	35.7 (25.2–50.5)	0.11
	Control	13	83.5 (28.7–242.8)**	
13 months	**Boostrix-IPV**	22	7.6 (4.5–12.8)	0.09
	Repevax	15	3.9 (2.0–7.6)**	
	Either Vaccine	37	5.8 (3.8–8.7)	0.0006
	Control	11	36.1 (16.0–81.2)**	

*K-wallis test, **95% CI are approximate due to small sample size and skewed data

3.1. Antibody titres post-primary immunisation in those with pre- or post-booster results

Of those recruited to iMAP3 with preschool booster results available, there was no significant difference in poliovirus neutralising antibody titres post-primary immunisations between children born to mothers immunised with Boostrix- IPV and children born to mothers immunised with Repevax at both 5 months (GMT 30.0 vs GMT 44.1, $p = 0.33$) and at 13 months (GMT 7.6 vs GMT 3.9, $p = 0.09$). However, antibody titres were significantly lower in children born to immunised mothers compared with unimmunised mothers at 13 months (GMT 5.8 vs GMT 36.1, $p = 0.0006$), despite differences not reaching significance in the period immediately post primary immunisation (GMT 35.7 vs GMT 83.5, $p = 0.11$) [Table 1].

3.2. Antibody titres prior to preschool booster

Prior to receipt of the preschool booster no significant difference was found between children born to mothers immunised with Boostrix-IPV versus Repevax. Children of unvaccinated mothers had significantly higher GMTs of antibodies compared with children of vaccinated mothers (54.7 vs 4.3, $p = 0.0001$), with 80% compared with 42% having protective antibody titres (≥ 8) ($p = 0.016$) and 93% vs 51% having titres ≥ 4 ($p = 0.005$) [Table 2].

The GMTs of children born to unvaccinated mothers, and those born to mothers vaccinated with Repevax, were (non significantly) higher prior to the preschool booster than when measured at 13 months of age in the same children (GMT 54.7 vs GMT 36.1 and GMT 4.9 vs GMT 3.9, respectively). On analysis of individual participant results it was found that 2 participants in the unvaccinated maternal arm and 3 participants in the Repevax vaccination arm demonstrated at least a four-fold increase in antibody titre [Supplementary chart]. Of note, removal of these outliers makes no difference to the statistical significance of the results.

3.3. Antibody titres post preschool booster

One month following the preschool booster all children had antibody titres ≥ 8, regardless of whether their mothers were immunised with Boostrix-IPV, Repevax or not immunised. Children of vaccinated mothers had significantly lower GMT compared with children of unvaccinated mothers (988 vs 2964, $p = 0.009$). There was no significant difference in GMT between children born to Boostrix-IPV or Repevax vaccinated mothers [Table 3].

The polio antibody results for all timepoints (5 months, 13 months, pre-preschool booster, post-preschool booster) for all children are displayed in Fig. 1.

4. Discussion

Prior work established a reduced response to the poliovirus primary immunisation series between infants whose mothers receive a dTaP-IPV vaccine in pregnancy and those whose mothers do not, which persists until at least 13 months of age [5]. To our knowledge, whether this immunity gap continues through until preschool age has not been assessed.

At 3 years and 4 months of age, children born to vaccinated mothers (regardless of the IPV-containing vaccine received) have significantly lower poliovirus specific antibody titres, with over half lacking GMTs ≥ 8, the proposed correlate of protection [12–14], when compared with children born to unvaccinated mothers. This represents a potential vulnerability of children aged up to 3 years to 4 months. Encouragingly, following the preschool booster, all children, regardless of study arm, have a significant rise in poliovirus specific neutralising antibodies to above the titres associated with protection. However, a significant difference in antibody titre between children born to unvaccinated mothers compared to vaccinated mothers is still evident post-booster vaccine.

Table 3
Serum neutralising antibodies against poliovirus post receipt of preschool booster in children born to mothers given Boostrix-IPV, Repevax or no DTaP-IPV in pregnancy. The GMT and proportion with antibodies at a titre of ≥ 4 and ≥ 8 are shown; The denominator is the number of children with a sufficient sample volume to complete the neutralisation assay.

Group	GMT (95% CI)	P-value*	No. ≥ 4 (%)	No. ≥ 8 (%)
Boostrix-IPV	833 (438–1585)	0.27	22/22 (100%)	22/22 (100%)
Repevax	1217 (534–2776) **		18/18 (100%)	18/18 (100%)
Either Vaccine	988 (604–1616)	0.009	40/40 (100%)	40/40 (100%)
Control	2964 (1779–4937) **		15/15 (100%)	15/15 (100%)

*K-wallis test, **95% CI are approximate due to small sample size and skewed data.

Table 2
Serum neutralising antibodies against poliovirus prior to receipt of preschool booster in children born to mothers given Boostrix-IPV, Repevax or no DTaP-IPV in pregnancy. The GMT and proportion with antibodies at a titre of ≥ 4 and ≥ 8 are shown; The denominator is the number of children with a sufficient sample volume to complete the neutralisation assay.

Group	GMT (95% CI)	P-value*	No. ≥ 4 (%)	P-Value**	No. ≥ 8 (%)	P-Value**
Boostrix-IPV	3.8 (2.2–6.4)	0.66	12/24 (50%)	1	10/24 (42%)	1
Repevax	4.9 (2.5–9.8)***		11/21 (52%)		9/21 (43%)	
Either Vaccine	4.3 (2.8–6.5)	0.0001	23/45 (51%)	0.005	19/45 (42%)	0.016
Control	54.7 (15.4–194.6)***		14/15 (93%)		12/15 (80%)	

*K-wallis test, ** exact P-value, *** 95% CI are approximate due to small sample size and skewed data.

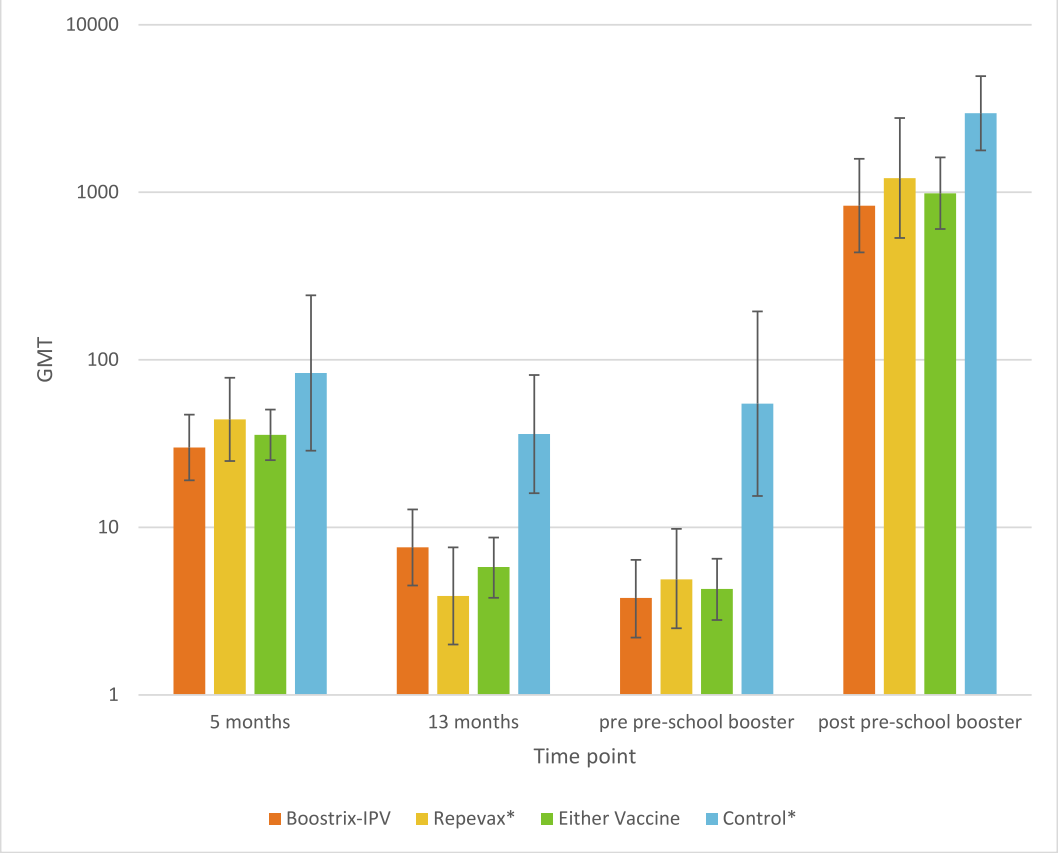

Fig. 1. GMTs of poliovirus neutralising antibody with 95% confidence intervals at all time points (5 months, 13 months, pre-preschool booster, post-preschool booster) in children born to mothers given Boostrix-IPV, Repevax, either vaccine, or no DTaP-IPV vaccine in pregnancy. *95% CI are approximate due to small sample size and skewed data.

Ongoing surveillance is required to see if this difference has clinical significance and whether it persists until the next scheduled booster dose in the UK given at 13–14 years of age (the "school-leaving booster").

Interestingly, five children showed at least a four-fold increase in poliovirus specific antibody titres between 13 months of age and the preschool booster age, two in the maternal-unvaccinated group, and three in the maternal vaccinated group. For these children, there was no corresponding increase in pertussis antibody concentrations (data not shown), indicating that they had not inadvertently received the pre-school booster. In one participant, we were able to confirm receipt of an oral poliovirus vaccine whilst abroad. However, we were unable to identify a new exposure to poliovirus (infection or vaccine) in any of the other participants, although we may speculate that they have had contact with a recipient of oral polio vaccine [8,19].

Since this study was conducted, the JCVI has updated recommendations to the UK immunisation programme. Firstly, it advised a preference for a non-IPV containing pertussis vaccine to be given as part of the maternal vaccination programme [10]. This change is supported by our data demonstrating that the reduced poliovirus specific neutralising antibody titres seen in children of IPV-vaccinated mothers after the primary series persist until receipt of the pre-school booster. Other studies have also shown reduced infant antibody responses to heterologous vaccine antigens including polio, if mothers receive dTaP vaccines antenatally [20,21]. These studies have several limitations including small sample sizes [20] and non-randomised vaccine allocation [21], with evidence of baseline differences in infant poliovirus specific antibody concentrations between maternal immunisation groups. Therefore, the impact of maternal non-IPV dTaP vaccination on poliovirus specific antibody levels in infants remains uncertain.

Secondly, the JCVI recommended the introduction of a booster dose of a polio-containing vaccine at 18 months of age [22]. We anticipate that most children receiving the 18-month hexavalent vaccine will now have had mothers vaccinated antenatally with a non-IPV-containing pertussis vaccine. However, the introduction of the additional hexavalent vaccine at 18 months may still be beneficial in terms of immunity to poliovirus given that in this study 20% of children born to unvaccinated mothers were found to have titres below the protective threshold for polio at preschool age. Moreover, the JCVI recommend the continuation of the polio vaccine booster campaign for children aged 1–9 years old in London. This campaign will include children who have had mothers receiving a pertussis-containing IPV vaccination antenatally as per our study cohort. This may be of particular benefit to children who receive this booster prior to receiving the pre-school booster (i.e. children aged 1–3 years 4 months), given that in this study we see only 42% of children of dTaP-IPV vaccinated mothers have titres above the protective threshold at this age. Whether the optimum timing of an IPV-containing booster vaccine is at 12-months of age or 18-months of age will be influenced by other considerations, for example related to pertussis immunity [2].

There are some limitations to this study. Firstly, the sample size is relatively small due to the restricted pool of potential participants and loss to follow up, which reduced the statistical power of the analysis.

Moreover, data were not available for all children at both timepoints due to inadequate blood sample volumes. Secondly, the group of children born to unvaccinated mothers was a convenience sample and not subject to randomisation. This may introduce systematic differences; however, we expect these to be minimal and there was no significant difference in baseline characteristics between these groups.

In conclusion, this is the first study to examine the effect of a polio containing pertussis vaccination given antenatally on children's immune responses at preschool age. In this study there is evidence that the majority of children whose mothers received a dTaP-IPV vaccine antenatally, and some children whose mothers did not receive this vaccine, have serum poliovirus neutralising antibodies below the correlate of protection at pre-school age. This supports the JCVI recommendation for removing the IPV component of the antenatal pertussis vaccine, and introduction of an IPV containing booster at 18 months respectively. For children who were vaccinated as per the schedule examined in this study, further research is required on the duration of protection conferred following the pre-school booster.

CRediT authorship contribution statement

Kajal Radia: Writing – review & editing, Writing – original draft. **Shari Sapuan:** Writing – review & editing. **Nicholas Grassly:** Writing – review & editing. **Nick Andrews:** Writing – review & editing, Formal analysis, Data curation. **Mary Ramsay:** Writing – review & editing, Conceptualization. **Vanessa Saliba:** Writing – review & editing. **Laura Stephens:** Writing – review & editing, Resources, Investigation. **Javier Martin:** Writing – review & editing, Resources, Investigation. **Christine Jones:** Writing – review & editing, Methodology, Conceptualization. **Elizabeth Miller:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Paul T. Heath:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: MR reports a relationship with UKHSA that includes: funding grants. CEJ has conducted studies on behalf of University of Southampton and University Hospital Southampton NHS Foundation Trust funded by vaccine manufacturers, including Minervax, Moderna, within the last 3 years, but receive no personal funding from these sources. CEJ has conducted studies on behalf of the University of Southampton and University Hospital Southampton NHS Foundation Trust funded by vaccine manufacturers, including Pfizer, Minervax, Moderna, within the last 3 years, but receive no personal funding from these sources. She has received grant funding from the MRC [grant number MR/Y033752/1]. CEJ been a member of data safety and monitoring board for Moderna, for which she received remuneration. MR's directorate at UKHSA has provided vaccine manufacturers with post-marketing surveillance reports on meningococcal, Haemophilus influenzae, and pneumococcal infections, which the companies are required to submit to the UK Licensing Authority in compliance with their risk management strategy. A cost recovery charge is made for these reports. NG receives research funding from the Gates Foundation to work on poliovirus epidemiology and surveillance tools; NG is also a member of JCVI. KR is a contributor to intellectual property licensed by Oxford University Innovation to Astra Zeneca. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2026.128306.

Data availability

Data will be made available on request.

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