Trials

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Motivations for paediatric vaccine trial participation

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During the COVID-19 pandemic, clinical trials of vaccines received unprecedented publicity; whether this interest might be transferred to vaccine trials generally is unknown. Enrolment in paediatric COVID19 vaccine trials was slower than uptake of adult vaccine trials, and lessons learned are, therefore, of importance for future recruitment and participant experience. Previous studies have investigated motivations for participation in adult vaccine trials [1, 2], paediatric trials for chronic conditions [3], and select paediatric vaccine trials [4]. By contrast, for a non-COVID-19 paediatric vaccine trial, with recruitment from March–May 2021, we noted a higher rate of response (5·71%) than we have seen previously in the same population. The study was a randomised controlled trial of acellular vs whole cell pertussis vaccines (AWARE, part of the Periscope consortium). 295 responses were received; 184 respondents volunteered to participate, and 112 infants met the inclusion/exclusion criteria. For our study on trial motivations, 110 surveys were sent out and 81 responded (73·6% response rate). Baseline characteristics of the trial participants' parents are outlined in Supplementary Table 1.

Previously, we have observed response rates of 2%-4% for similar trials. We therefore hypothesised that prior vaccine trial experience and exposure might modulate the threshold for trial participation, and descriptively studied motivations and barriers to paediatric vaccine trial participation in this context. Ethical approval and feedback from the Oxford Vaccine Centre Public and Patient Involvement (PPI) group was received. Motivations for trial participation were dichotomised by prior trial participation (Table 1); self-described altruistic motivations were common, while motivations related to concrete personal benefits, regardless of prior trial participation, were less frequently reported. The two most cited motivations were improving the health of children and contributing to scientific progress, while access to in-home study visits was reported as a motivator by 83% of respondents. The pandemic context may have contributed to both the emphasis on scientific progress and the sense of public service and interest in trials, while also heightening the perceived benefit of in-home visits.

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Table 1 Motivations for trial participation. *P*-values are for two-sample t-tests, without a correction for multiple comparisons

	Overall (*n* = 81)	Prior Trial Experience (*n* = 16)	No Prior Trial Experience (*n* = 65)	*P* value
Direct benefits to child				
Vaccine access—protective	28 (34·6%)	4 (25·0%)	24 (36·9%)	0·38
Paediatrician access	39 (48·15%)	6 (37·5%)	33 (51·6%)	0·35
Immunisations at home	67 (82·7%)	10 (62·5%)	57 (87·7%)	0·02
GP appointments difficult	7 (8·64%)	1 (6·25%)	6 (9·23%)	0·71
Safer to receive vaccines at home	33 (40·74%)	5 (31·25%)	28 (43·08%)	0·39
Altruism/ societal benefits				
Improve health of children	79 (97·53%)	16 (100%)	63 (96·92%)	0·48
Scientific progress	80 (98·77%)	16 (100%)	64 (98·46%)	0·62
Others view positively	21 (25·93%)	6 (37·50%)	15 (23·08%)	0·24
Friends/ family positive reaction	57 (70·37%)	10 (62·50%)	47 (72·31%)	0·45
Clinical trial experience				
Wanted trial experience	40 (49·38%)	7 (43·75%)	33 (50·77%)	0·62
COVID changed my view	23 (28·40%)	6 (37·50%)	17 (26·15%)	0·37
Pertussis-Specific Concerns				
Comforted: vaccine previously approved in UK	77 (95·06%)	16 (100%)	61 (93·85%)	0·31
Comforted: vaccine approved by WHO	78 (96·30%)	16 (100%)	62 (95·38%)	0·39
Side effects worth improved efficacy	79 (97·53%)	15 (93·75%)	64 (98·46%)	0·28
Worried re severe reaction	14 (7·28%)	2 (12·50%)	12 (18·46%)	0·58
Worried about long term health effects	1 (1·23%)	0 (0%)	1 (1·54%)	0·62

This survey has limitations, being an unvalidated survey instrument, the reliance on self-report, and the inability to ascertain motivations among those who declined to participate. Further research including representative sample of the general UK population and better controlling for social desirability bias may shed further light on the nature and magnitude of differences in motivation, providing a basis for targeting adjustments to enrolment—and improve generalisability especially post-pandemic. Parental motivations for enrolling children in clinical trials are understudied and merit detailed exploration to maximise successful recruitment in future trials.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-023-07597-2.

Additional file 1: Supplementary Table 1. Baseline characteristics of 81 respondents. *P*-values are for chi-squared tests.

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Authors' contributions
KH Conceptualised and designed the survey, led and coordinated recruitment of all participants, data collection and validation, literature search and manuscript writing. JK performed formal data analysis, literature search and equal contribution to the manuscript writing as KH. MMVP was involved in the initial study design and reviewed and edited the manuscript. AP had an overview of the project and reviewed and edited the manuscript. DK is the principal investigator of the trial, provided conceptual and technical guidance on survey design, supervision and reviewed and edited the manuscript. SV conceptualised and designed the survey, data collection and validation, literature search, data analysis and provided the overall supervision of the manuscript writing. All authors critically reviewed and approved the final text and were responsible for the decision to submit the manuscript.

Declarations

Competing interests
All other authors declare no competing interests.

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References

1. Detoc M, Launay O, Dualé C, et al. Barriers and motivations for participation in preventive vaccine clinical trials: Experience of 5 clinical research sites. Vaccine. 2019;37(44):6633–9.

2. Detoc M, Gagneux-Brunon A, Lucht F, Botelho-Nevers E. Barriers and motivations to volunteers' participation in preventive vaccine trials: a systematic review. Expert Rev Vaccines. 2017;16(5):467–77.
3. Brooks SP, Bubela T. Application of protection motivation theory to clinical trial enrolment for pediatric chronic conditions. BMC Pediatr. 2020;20(1):123-.
4. Chantler TEA, Lees A, Moxon ER, Mant D, Pollard AJ, Fiztpatrick R. The role familiarity with science and medicine plays in parents' decision making about enrolling a child in vaccine research. Qual Health Res. 2007;17(3):311–22.

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