Determining whether mass vaccination campaigns with fractional dose of PCV10 (Pneumosil®) could accelerate herd protection against pneumococcal transmission in sub-Saharan Africa

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Background
In settings with low Pneumococcal Conjugate Vaccine (PCV) coverage, mass campaigns targeting multi-age cohorts (MAC) might accelerate herd protection but would be costly. Campaigns using fractional dose PCV would decrease cost and increase access.

Methods
We conducted a cluster-randomized trial in Niger to evaluate the effect of a mass campaign targeting children aged 1-9 years on pneumococcal carriage. 63 villages were randomized in a 3:3:1 ratio to receive campaigns with a single full dose of a 10-valent PCV (Pneumosil®), a single 1/5th fractional dose, or no campaign. We conducted two independent carriage surveys among a total of 2268 households 6 months before and 6 months after vaccination, collecting a nasopharyngeal swab from a child aged 1-9 years for culture and serotyping. If the full-dose campaign was shown superior to control in carriage reduction, the non-inferiority of fractional-dose campaign was to be evaluated, with the lower bound of the 95%CI > -7.5%. Registration: NCT05175014, PACTR20211257448484

Results
Surveys were conducted between December 22, 2021, and 18 March, 2022, and December 12, 2022, and March 9, 2023. The vaccination campaign was June 15-August 2, 2022. Participant characteristics were similar between the two surveys and across arms. Pre-vaccination, vaccine-type (VT) carriage was 15.6% in the full-dose arm, 17.9% in the fractional dose arm, and 18.8% in the control arm. Post-vaccination, VT carriage was 4.6% in the full-dose arm, 8.0% in the fractional dose arm, and 16.5% in the control arm. In the primary analysis, the risk difference between the full dose and the control arms was -12.0% [-19.0; -5.0], p=0.001, and between the full dose and fractional dose arms it was -3.5% [-5.8; -1.1], meeting the prespecified non-inferiority criterion. Similar results were seen after adjustment for age, vaccine coverage and other factors.

Conclusion
MAC campaigns had a marked impact on VT carriage and fractional-dose campaigns met non-inferiority criteria. Such campaigns should be considered in low-coverage settings, including humanitarian emergencies, to accelerate population protection.