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Immunogenicity and safety of a pentavalent (ACYWX) meningococcal conjugate vaccine in the infant Expanded Program on Immunization

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Background

The introduction of the monovalent serogroup A meningococcal conjugate vaccine (MenAfriVac) in sub-Saharan Africa, since 2010, has significantly reduced serogroup A disease in the meningitis belt. However, serogroups C, W, and X remain substantial etiologic causes of meningitis. Existing quadrivalent meningococcal conjugate vaccines lack serogroup X. NmCV-5 developed by Serum Institute of India represents an affordable and scalable pentavalent vaccine intended to protect against serogroups A, C, W, Y, and X. NmCV-5 has nearly completed clinical development and is under review for WHO pre-qualification (PQ).

Aim/Methods

This is a double-blind, randomized, controlled phase 3 study designed to evaluate the non-inferiority of NmCV-5 against MenACWY-TT in terms of Rabbit serum bactericidal antibody (rSBA) titers in Malian infants. Infants were randomly assigned (2:1 ratio) to receive a single dose of either NmCV-5 or MenACWY-TT vaccine at 9 or 15 months of age. A secondary aim is to establish non-interference in immune responses to the Expanded Program on Immunization (EPI) vaccines in terms of antibody responses against measles, rubella, and yellow fever. Safety is monitored throughout the study. This study was approved by the ethical committees in Mali and the United States. This abstract represents interim data from the 9-month infant group; data from the 15-month infant group is not yet available.

Results

A total of 602 Malian infants age 9-months received NmCV-5 or MenACWY-TT. No serious adverse events related to study product have been observed and the independent safety monitoring committee has not identified any safety concerns. rSBA titers and antibody responses against measles, rubella, and yellow fever are not available at the time of the submission of the abstract but are to be available in September 2023.

Conclusions

This phase 3 study is designed to provide evidence that NmCV-5 is immunogenic in infants at 9 months of age and also document that concomitant vaccination of NmCV-5 does not affect the immune responses of EPI vaccines. Based on these data, the vaccine can be introduced in the EPI schedules of endemic countries. This is the final study required to support WHO-PQ.