

1084. Persistence of Meningococcal Antibodies and Response to a Booster Dose after a Two-dose Vaccination Series with Investigational MenABCWY Vaccine Formulations in Adolescents

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Background. Novartis has developed a glycoconjugate vaccine against *Neisseria meningitidis* serogroups A, C, W and Y (MenACWY-CRM), and a recombinant protein vaccine against serogroup B, and is now evaluating different formulations of a MenABCWY vaccine combining antigens against all 5 serogroups (clinicaltrials.gov NCT01367158).

Methods. Among adolescents aged 11–18 years who had previously received 2 doses (0 and 2 months) of four different MenABCWY vaccines (with varying B components) or control vaccines, 440 subjects were enrolled to examine immune response to a third dose (4 months after dose 2), and antibody persistence 10 months after a 2-dose series. Antibodies against A, C, W, Y and B antigens were measured by serum bactericidal assay with human complement (hSBA). Frequencies of local and systemic reactions and other adverse events were assessed.

Results. Prior to dose 3, 92–100% of subjects in all MenABCWY groups had hSBA titers ≥ 8 against serogroups C, W and Y, and 52–79% against A. One month after dose

3, 96–100% of subjects in all MenABCWY groups had hSBA titers ≥ 8 against A, C, W, and Y. After dose 3, percentages of subjects with hSBA titers ≥ 5 against serogroup B test strains increased across MenABCWY groups, with highest percentages (87%–100%) being in subjects who received a MenABCWY vaccine containing outer membrane vesicles (OMV).

Persistence of antibodies against A, C, W and Y, 10 months after dose 2 of MenABCWY was similar for all groups, and was at least equal to that after one dose of MenACWY-CRM. For all MenABCWY groups, antibody titers against B test strains declined most rapidly within 4 months after dose 2, and then declined gradually over the subsequent 6 months. Overall, the OMV-containing MenABCWY vaccines had the highest GMTs over time against most B test strains.

Most frequent solicited reactions were injection site pain (71%), myalgia (42%), and headache (33%). OMV-containing MenABCWY groups had higher frequencies of local reactions, myalgia, and arthralgia.

Conclusion. All MenABCWY vaccine formulations elicited robust immune responses to A, C, W, Y, and B after a third dose. Subjects given OMV-containing MenABCWY vaccines had the highest antibody titers against serogroup B test strains 10 months after dose 2.

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