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Antibody persistence 22 months after vaccination of adolescents with the Novartis investigational meningococcal ACWY-CRM197 conjugate vaccine or Menactra®

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Background: Improved primary response, induction of immunologic memory and antibody persistence are key attributes of conjugate vaccines. We have previously presented immunogenicity data one month post-vaccination from a phase III, randomized, observerblind comparative study of an investigational meningococcal ACWY-CRM197 conjugate vaccine (MenACWY-CRM, Novartis) or Menactra® (MCV-4, Sanofi Pasteur). Data from approximately two years post-vaccination in an ongoing long-term study of persistence of bactericidal antibodies are now available.

Methods: Subjects, who were aged 11-18 years when enrolled into the parent study, were approached for enrollment. Age-matched meningococcal vaccine-naïve subjects were enrolled to serve as additional controls. The primary objective was to assess the persistence of immune response for each serogroup using a serum bactericidal assay with human complement (hSBA), expressed as the proportions of subjects with a titer $\geq$1:8 and Geometric Mean Titers (GMTs).

Results: At a median of 22 months post vaccination, 278 MenACWY-CRM and 191 MCV-4 subjects, plus 128 naïve controls were enrolled. For serogroups A, C, W and Y respectively, the proportions of subjects with hSBA $\geq$1:8 were: 36%, 62%, 84%, and 67% for MenACWYCRM; 25%, 58%, 74%, 54% for MCV-4; and 5%, 42%, 51% and 40% for the naïve controls. Similarly hSBA GMTs for serogroups A, C, W and Y, respectively, were: 5.3, 10.0, 18.0 and 12.0 for MenACWY; 3.6, 8.7, 14, and 7.9 for MCV-4; and 2.4, 6.0, 7.8 and 5.1 for the controls. Compared with MCV-4 recipients, the proportions of MenACWY-CRM vaccinees with hSBA $\geq$1:8 was significantly higher for serogroups A, W and Y; GMTs were significantly higher for serogroups A and Y. Compared with naïve controls, GMTs were significantly higher for MenACWY-CRM for all four serogroups.

Conclusion: A majority of adolescents maintain bactericidal antibody titers above 1:8 against meningococcal serogroups C, W and Y two years after receiving either conjugate vaccine although more of the MenACWY-CRM vaccinees still had protective antibody titers against serogroups A, W, and Y than those who received MCV-4.

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KNOW ESSENTIALS — A novel algorithm for informed vaccine-related decision-making in developing countries

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Background: In most developing countries, vaccine-related decisions are seldom evidencebased and health-care stakeholders (physicians/policy-makers/patients) usually do not have access to locally relevant health technology assessment (HTA), in contrast to developed countries. The objective was to develop a decision-making algorithm facilitating informed vaccinerelated decisions by various stakeholders in developing countries, using available information from literature.

Methods: KNOW ESSENTIALS is an acronym for 13 components to be evaluated for informed vaccine-related decisions. The first three defining criteria (acronym KNOW) are establishment of (i)Knowledge of need (KN) for the vaccine, (ii)Outcome of interest (O), (iii) Which stake-holder is involved (W). Subsequent components should be evaluated only when all three are clear. The other criteria (acronym *ESSENTIALS*) are: (iv)Evidence of effectiveness and/or efficacy, (v)Safety, (vi)Social quotient (consumer acceptability and ethical/legal/moral propriety), (vii)Economic issues viz cost and cost-effectiveness, (viii)Novelty (newness), (ix)Time to outcome of interest, (x)Integration with existing services/facilities, (xi)Alternate options, (xii)Likely impact of not choosing the intervention, and (xiii)Sustainability. Based on local and/or external data/information from literature, each of these is categorised as Red (unfavourable), Green (favourable), Yellow (insufficient/unclear data) or White (notapplicable). The basis for colour coding has been elaborately defined for each criterion to exclude subjectivity; but is not presented here for lack of space. Criteria (iv) to (vii) are mandatory criteria and stake-holders should proceed only if all are Green.

Table 1 shows practical application of the algorithm for a currently relevant, challenging decision: whether India should consider universal human papillomavirus(HPV) vaccination.

Results: The algorithm can be applied by multiple stake-holders (policymakers/physicians/patients/health-care payers) to make objective decisions for their setting based on explicit criteria; thus saving time and cost. It enables each stake-holder to arrive at an informed decision appropriate for them. Pilot testing considering various vaccines as well as different stake-holders suggests that it facilitates objective, reproducible, and transparent decision-making. A randomized trial comparing it against formal HTA is planned.

Conclusion: KNOW ESSENTIALS is a practical algorithm facilitating informed vaccinerelated decisions by various health-care stake-holders in developing country settings.