Administration of meningococcal vaccine with other routine infant vaccines appears effective

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Administration of routine infant immunizations with a vaccine for serogroup B Neisseria meningitidis, a bacterium that is a cause of serious disease such as sepsis and meningitis, was effective against meningococcal strains and produced minimal interference with the response to the routine vaccinations, according to a study in the February 8 issue of *JAMA*.

Certain serogroup B *Neisseria meningitidis* (MenB) vaccines proved effective in clinical trials and controlled a clonal MenB outbreak in New Zealand; however, the high strain specificity of these vaccines limited their usefulness, especially in infants and young children, according to background information in the article.

Nicoletta Gossger, M.D., of the University of Oxford, United Kingdom, and colleagues assessed the immunogenicity (the ability to produce an immune response) and reactogenicity (producing adverse reactions) of a vaccine developed to provide broader protection, a multicomponent serogroup B meningococcal vaccine (4CMenB), in a large group of infants, given in 2 different schedules, with or separately from routine vaccines. The multicenter, randomized controlled study included 1,885 infants enrolled at age 2 months from August 2008 to July 2010 in Europe. Participants were randomized to receive (1) 4CMenB at 2, 4, and 6 months with routine vaccines (7-valent pneumococcal and combined diphtheria, tetanus, acellular pertussis, inactivated polio,

hepatitis B, Haemophilus influenzae type b vaccines); (2) 4CMenB at 2, 4, and 6 months and routine vaccines at 3, 5, and 7 months; (3) 4CMenB with routine vaccines at 2, 3, and 4 months; or (4) routine vaccines alone at 2, 3, and 4 months. The primary outcome the researchers measured was the percentage of participants with human complement serum bactericidal activity (hSBA) titer (concentration) of 1:5 or greater against 3 MenB strains specific for vaccine antigens (NZ98/254, 44/76-SL, and 5/99).

After immunization with 4CMenB and routine vaccines together at either 2, 4, and 6 or 2, 3, and 4 months, 99 percent or more of participants had hSBA titers of 1:5 or greater for strains 44/76-SL and 5/99. For NZ98/254, this proportion was 79 percent for vaccination at 2, 4, and 6 months with routine vaccines, 86.1 percent for vaccination at 2, 4, and 6 months without routine vaccines, and 81.7 percent for vaccination at 2,3, and 4 months with routine vaccines. The predefined criteria of a sufficient immune response was met for all three strains.

Responses to routine vaccines given with 4CMenB were noninferior (outcome not worse than treatment compared to) to routine vaccines alone for all antigens, except for the responses to pertactin (a pertussis antigen) and the pneumococcal vaccine serotype 6B.

"Fever was seen following 26 percent to 41 percent of 4CMenB doses when administered alone, compared with 23 percent to 36 percent after routine vaccines given alone and 51 percent to 61 percent after 4CMenB and routine vaccines administered together," the authors write.

"In conclusion, 4CMenB was immunogenic, generally well tolerated, and showed minimal interference with routine vaccines in the first year of life. The flexibility in schedule allows it to be incorporated into a range of country-specific immunization schedules and for primary immunization to be completed in early infancy. If licensed, the decisions

regarding vaccine introduction will require detailed assessment of potential vaccine coverage at a regional level and monitoring after implementation to determine the accuracy of such predictions. Nevertheless, this vaccine could potentially provide improved protection for infants against meningococcal disease beyond the protection provided by currently licensed vaccines."

In an accompanying editorial, Amanda C. Cohn, M.D., and Nancy E. Messonnier, M.D., of the Centers for Disease Control and Prevention, Atlanta, write that "the potential of 4CMenB vaccine to reduce serogroup B meningococcal disease is substantial, but it cannot be compared with the success of conjugate vaccine programs."

"4CMenB vaccine may not reduce nasopharyngeal [pertaining to the cavity of the nose and the nasal parts of the pharynx] carriage or produce herd immunity, as the serogroup C conjugate vaccine did in the United Kingdom. Booster doses may be required to sustain protection but may not confer the same degree of immunologic memory as conjugate vaccines. Countries will have to weigh the benefits of serogroup B vaccination against the costs of adding vaccines to the infant schedule. However, the anticipated licensure of this vaccine in Europe and other countries means that for the first time vaccines to prevent all 5 of the serogroups that cause most meningococcal disease worldwide will be available."

More information: *JAMA*. 2012;307[6]:573-582.
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