Vaccine Combinations Appear Safe, Effective

BY MITCHEL L. ZOLER

PHILADELPHIA — Administering two or more vaccines simultaneously was safe and immunogenic in results from two separate studies reported at the annual meeting of the Infectious Diseases Society of America.

The results from combined administration of the human papillomavirus (HPV) vaccine; a vaccine for tetanus, diphtheria, and pertussis (Tdap); and a quadrivalent, conjugated meningococcal formulation (MCV4) are especially relevant to practice because all three are already approved for U.S. use, and the concept of delivering all three simultaneously received endorsement by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices in 2007 (MMWR 2007;56:1-24).

The only piece missing until now was data showing that the concomitant strategy was safe and immunogenic—something the new study now provides, said Cosette M. Wheeler, Ph.D., professor of pathology and obstetrics and gynecology at the University of New Mexico in Albuquerque.

Her study used Cervarix (HPV vaccine), Boostrix (Tdap), and Menactra (meningococcal vaccine). Cervarix and Boostrix are marketed by GlaxoSmithKline, which funded the study. Menactra is marketed by Sanofi Pasteur. in addition to receiving research support from GlaxoSmithKline, Dr. Wheeler also received funding for studies from Merck, which markets the HPV vaccine Gardasil, and from Roche Molecular Systems.

The study enrolled 1,283 healthy girls aged 11-18 years at 48 U.S. centers. The researchers randomized the participants to one of six different treatment

schemes: HPV vaccine only at months 0, 1, and 6; HPV with Tdap at month 0 followed by HPV only at months 1 and 6; HPV with the meningococcal vaccine at month 0 followed by HPV only at months 1 and 6; all three vaccines at month 0 followed by HPV only at months 1 and 6; Tdap only at month 0 followed by HPV only at months 1, 2, and 7; and MCV4 only at month 0 and then HPV only at months 1, 2, and 7.

The results showed that 1 month after the subjects received any of the concomitant doses, their immune responses all fell within the prespecified criteria for noninferiority, compared with the responses when the vaccines were administered individually.

Immune response in people who received vaccines simultaneously fell within the noninferiority limit.

DR. FRENCK

The second study examined concomitant administration of an investigational, 13-valent, conjugated pneumococcal vaccine and the trivalent, seasonal influenza vaccine of 2007-2008 in 1,106 healthy adults aged 50-59 years, said Dr. Robert W. Frenck Jr., professor of pediatrics at Cincinnati Children's Hospital Medical Center.

The pneumococcal vaccine was developed by Wyeth (which recently was acquired by Pfizer Inc.), which funded the study. Dr. Frenck had no other conflicts to disclose for his study.

He and his associates randomized subjects to receive either the pneumococcal and flu vaccines together at month 0 followed by placebo at month 1, or the flu vaccine and placebo at month 0 followed by the pneumococcal vaccine at month 1.

One month after vaccination, the immune responses to both vaccines in people who received them simultaneously fell within the prespecified noninferiority limit, compared with the responses in people who received the two vaccines 1 month apart, Dr. Frenck reported. Simultaneous administration also resulted in similar rates of local and systemic reactions compared with giving the vaccines 1 month apart. ■

Hospitalizations For Rotavirus Down by 86%

PHILADELPHIA — The rotavirus vaccine introduced in early 2006 worked as intended, cutting the U.S. rate of rotavirus-associated diarrhea requiring hospitalization in children younger than 2 years during July 2007–June 2008 by 86%, compared with rates during 2000-2006, according to an analysis of a large U.S. private insurance database.

"The first rotavirus season post vaccine introduction showed a substantial decline, to a level below the lowest rate of prior years," Dr. Jennifer E. Cortes said in an interview while presenting a poster at the annual meeting of the Infectious Diseases Society of America. "The reduction was lower than in the clinical trials …but it was still effective in the real world," said Dr. Cortes, an epidemic intelligence service officer in the division of viral diseases of the Centers for Disease Control and Prevention.

The data also showed a significant impact of rotavirus vaccination on the incidence of all diarrhea that led to hospitalization in children younger than 2 years during July 2007–June 2008, cutting this rate by 39%, compared with the average during 2000-2006.

Experience using the RotaTeq formulation since its U.S. introduction confirms its safety, with no unexpected reports of vaccine-associated adverse effects and no link with excess cases of intussusception, said Dr. Cortes, who had no financial relationships to disclose.

She and her associates analyzed records for about 2 million children younger than 5 years for the period 2007-2008.

The data showed that following RotaTeq's U.S. introduction in 2006, its use in children younger than 1 year gradually rose, reaching 63% coverage of children 11 months or younger by the end of December 2007, Dr. Cortes said.

With vaccine coverage at 63% during the midpoint of the July 2007–June 2008 rotavirus season studied, the 86% vaccine effectiveness rate seen was "greater than expected," she reported. The data also showed that hospitalization for rotavirus-associated diarrhea was reduced in older children, 2-4 years old, who never received rotavirus vaccination. These findings suggest a herd effect, Dr. Cortes said.

—Mitchel L. Zoler