Logistics, Financial Barriers Will Stymie HPV Vaccine's Impact

BY DAMIAN McNAMARA
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JACKSONVILLE, FLA. — Financial and logistic barriers will limit the implementation and impact of human papillomavirus vaccine, Dr. Lance Rodewald said at a conference on STD prevention sponsored by the Centers for Disease Control and Prevention.

New vaccines incorporated into the child immunization schedule are typically adopted quickly across the nation. "For adolescents, we don't do as well," Dr. Rodewald said. "For example, there is 74% coverage for the three shots for hepatitis B. It is better for MMR and Td [tetanus-diphtheria], but our adolescent platform is not well established now."

To improve distribution to those at highest risk, family physicians, obstetricians and gynecologists, and other primary care providers will be encouraged to join the federal government's Vaccines for Children (VFC) program. VFC pays for vaccinations for certain vulnerable children through age 18 years, including those on Medicaid, Native Americans or Alaska natives, the uninsured, and those insured without a vaccine benefit.

Underinsured children are not covered by VFC, nor are they covered in most cases by a smaller federal program—Section 317—or state funding. "My confidence in government funding starts and stops at the VFC program," said Dr. Rodewald, a pediatrician and director of the Immunization Services Division, National Immunization Program, at the Centers for Disease Control and Prevention.

"HPV [human papillomavirus] vaccine is certainly going to be delivered in a two-tiered system. There is no way around it unless something changes," he said.

Because of inadequate state and Section 317 funding, many states cannot purchase vaccine for underinsured children, resulting in the two-tiered policy. "There is some indication the president might increase funding to include underinsured children who could get vaccinated at federal public health sites—but it's unlikely to happen this year," he said.

Financing the HPV vaccine for women over age 18 is another challenge. "The provider may have to purchase adult vaccines up front and get reimbursed later. So there is a financial risk if the vaccine is not used," Dr. Rodewald said.

The vast majority of Section 317 program funding, 95%, goes to vaccines for children. However, this means only 5% of Section 317 money pays for adult immunization, and state funding for adults is discretionary.

The financial considerations are not unique to HPV prevention. Other new vaccines likely coming soon include a second-dose varicella product and protection against shingles/postherpetic neuralgia, Dr. Rodewald said. "These new vaccines are great, but they come at a cost," he said. The cost to protect each child has grown from $45 in 1985 to $155 in 1995 to $837 in 2006.

"The U.S. immunization system is highly effective and highly successful at protecting children from vaccine-preventable diseases," Dr. Rodewald said. "But the most important stress in the U.S. system is financing access to the many new vaccines." ■

Immunity Redefined

Mumps *from page 1*

In the specially convened meeting—the results of which are considered interim—the committee redefined evidence of immunity to mumps through vaccination as follows: one dose of a live mumps virus vaccine for preschool children and adults not at high risk; two doses for children in grades kindergarten through 12 and adults at high risk (such as persons who work in health care facilities, international travelers, and students at post–high school educational institutions). Other criteria for evidence of immunity (such as birth before 1957, documentation of physician-diagnosed mumps, or laboratory evidence of immunity) remain unchanged. Health care facilities should consider recommending one dose of MMR vaccine to unvaccinated health care workers born before 1957 who do not have other evidence of mumps immunity.

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During an outbreak and depending on its epidemiology, a second dose of vaccine should be considered for adults and for children aged 1-4 years who have received one dose. The second dose should be administered as early as 28 days after the first dose. During an outbreak, health care facilities should strongly consider recommending two doses of MMR vaccine to unvaccinated workers born before 1957 who do not have other evidence of mumps immunity. ■

Menactra in Short Supply; Target High-Risk Groups

College freshman living in dorms and adolescents entering high school are moving to the head of the line to receive Menactra, following an announcement from the manufacturer that the company won't be able to meet demand for the meningococcal vaccine at least through this summer.

The Centers for Disease Control and Prevention announced in May that Sanofi Pasteur Inc., maker of the tetravalent meningococcal polysaccharide-protein conjugate vaccine (MCV4), expects demand for the vaccine to exceed supply (MMWR May 19, 2006;55[Dispatch]:1).

In response, the CDC—in conjunction with the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College Health Association, and the Society for Adolescent Medicine—recommends that providers continue to vaccinate adolescents entering high school (if they have not been previously vaccinated) and college freshman living in dorms. The company anticipates that enough MCV4 will be available to meet demand for these two groups, based on current supply projections.

Vaccination of children aged 11-12 years should be deferred until further notice. If possible, physicians should track any children in this age group, for whom MCV4 vaccination has been deferred, and recall them when the supply improves.

Other high-risk groups that should be vaccinated include: military recruits, travelers to areas where meningococcal disease is hyperendemic or epidemic, microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*, individuals with anatomic or functional asplenia, and individuals with terminal complement deficiency.

For periodic updates of vaccine supply, visit www.cdc.gov/nip/news/shortages/default.htm.

Physicians with questions about their orders should contact Sanofi Pasteur by calling 800-822-2436 or by visiting www.vaccineshoppe.com.

—Kerri Wachter

Studies Shed Light on Hepatitis C Therapy Combos, Nonresponders

BY MARY ELLEN SCHNEIDER
Senior Writer

LOS ANGELES — Extended combination therapy with consensus interferon for 72 weeks appears to help improve the viral response of patients with chronic hepatitis C who have previously relapsed after a 48-week course of treatment, according to a study presented at the annual Digestive Disease Week.

The investigator-initiated study, conducted by researchers from the University of Tübingen in Germany, showed that at the end of 72 weeks of daily therapy, the majority of patients treated with a combination of either consensus interferon plus ribavirin or pegylated interferon alfa-2a plus ribavirin had a reduction in hepatitis RNA. However, the drop was not statistically significant, said the lead study author, Dr. Stephan Kaiser, a professor of medicine at the university.

The investigators compared the two interferon combinations in 81 patients who had experienced a previous relapse after a standard 48 weeks of pegylated interferon plus ribavirin. At the end of week 72, 89% of patients taking the consensus interferon combination were in remission, compared with 76% of the pegylated alfa-2a interferon group.

But relapse rates remained high in the study, Dr. Kaiser said. The pegylated alfa-2a interferon combination had significantly higher rates of relapse than the consensus interferon combination. About 44% of patients in the pegylated alfa-2a interferon combination group had a sustained viral response after completing treatment, compared with 69% of the consensus interferon group.

Overall, the study indicated that treatment for relapse can be successful using consensus therapy for an extended period, but more research is needed in multicenter trials, Dr. Kaiser said.

Researchers also presented new data on treatments for another difficult-to-treat population: nonresponders. Interim results from an ongoing phase II multicenter trial show that a combination of valopicitabine (NM283) at high doses plus pegylated interferon can reduce hepatitis RNA at 24 weeks of treatment, reported Dr. Paul Pockros of Scripps Clinic in California and his colleagues.

The five-arm study compares valopicitabine alone to three different doses of valopicitabine (400 mg/day, 800 mg/day, and dose-ramping from 400 to 800 mg/day) with pegylated interferon, and pegylated interferon plus ribavirin as a control.

Valopicitabine, manufactured by Idenix Pharmaceuticals, is the first nucleotide-type HCV polymerase inhibitor to advance to phase II trials. The study is funded by the drug maker.

The best results—about a 3-log decrease in hepatitis RNA—were achieved with the 800-mg dose of valopicitabine plus pegylated interferon. However, some patients experienced vomiting and nausea at initiation of treatment, and three patients were hospitalized with dehydration, so researchers stopped using the 800-mg dose and are continuing with 200-mg and 400-mg doses of the drug.

The results with the combination of 400 mg of valopicitabine and pegylated interferon were less promising in the nonresponder study population, with about a 2.5-log decrease, Dr. Pockros said.

Continued treatment is needed to find out if there will be a sustained response with the new drug combination, Dr. Pockros said, and to find out if the drug will be more effective for preventing relapse than are current therapies. ■