

Payment Issues Could Limit HPV Vaccine Use

BY DAMIAN McNAMARA
Miami Bureau

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, primary care physicians and ob.gyns. 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.

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

wald, a pediatrician and director of the Immunization Services Division, National Immunization Program, at the Centers for Disease Control and Prevention.

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 financial considerations are not unique to HPV prevention. Other new vaccines likely to come 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." ■

HSV-2 Not Likely To Be a Cervical Cancer Cofactor

ATLANTA — Herpes simplex virus-2 does not appear to be a cofactor of human papillomavirus in the development of cervical cancer, Dr. Manuela Zereu reported at the annual meeting of the American Society of Clinical Oncology.

Human papillomavirus (HPV) is well established as an infection that is central to the pathogenesis of invasive cervical cancer, but because many women with HPV do not develop this cancer, it is believed certain cofactors play a role in disease development.

Some studies have suggested HSV-2 is one such cofactor, and in vitro experiments have shown a synergistic interaction between HSV-2 and HPV, but the findings of the current study did not bear this out, Dr. Zereu of the Santa Casa Cancer Center in Porto Alegre, Brazil, said in a poster presentation.

For the study, paraffin-embedded tissue samples from 229 patients diagnosed with adenocarcinoma of the uterine cervix between 1995 and 2003 were tested. DNA extraction showed that HPV was present in 79% of specimens, including HPV-18 in 51% of cases and HPV-16 in 34% of cases. However, all samples were negative for HSV-2 DNA.

—Sharon Worcester

new



Introducing Levemir®:
a long-acting basal insulin
with a light touch

New Levemir: for your patients who need a safe and effective way to improve A1C control

With proven reductions in A1C and FPG levels over time, Levemir can help your patients get to goal with up to 24 hours of glycemic control. Patients with diabetes can experience a consistent blood glucose response from injection to injection. Less weight gain was observed with Levemir in 12 of 12 clinical trials.* And Levemir is available in the Levemir® FlexPen®. FlexPen is the world's #1 selling prefilled insulin pen. So start your patients with diabetes on Levemir, and help them experience the light side of basal insulin.

Levemir is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Important safety information
Levemir should not be diluted or mixed with any other insulin preparations. Levemir is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Any change of insulin dose should be made cautiously

and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Levemir is not to be used in insulin infusion pumps. Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir from other intermediate or long-acting insulin preparations. The dose of Levemir may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients

in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation.

*Whether these observed differences represent true differences in the effects of Levemir and NPH insulin is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.



new
Levemir®
insulin detemir (rDNA origin) injection
Lighter years ahead



novo nordisk®

Reference: 1. IMS Health, IMS MIDAS [12 months ending September 2005]. Please see brief summary of Prescribing Information on adjacent page. FlexPen and Levemir are registered trademarks of Novo Nordisk A/S.

© 2006 Novo Nordisk Inc. 130299R1 May 2006