Race a Factor in Completing HPV Vaccine Series

VITALS

Major Finding: Eleven percent of girls who self-identified as black received all three doses of the HPV vaccine, compared with 22% of the white girls and 15% of those identified as other races.

Data Source: A retrospective review of medical records on 3,297 girls between ages 9 and 26 years, and who received the first HPV vaccine dose between June 2006 and June 2008 from an urban, academic, pediatric medical center with multiple primary care and specialty clinics.

Disclosures: None was reported.

BY DEBRA L. BECK

FROM THE ANNUAL MEETING OF THE SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE

TORONTO — Girls who identified themselves as white were twice as likely as those who identified themselves as black to complete the three-shot vaccination series against the human papillomavirus, according to a retrospective review of medical records.

"This is concerning because, historically, black women have had lower rates of cervical cancer screening and been more at risk from dying of cervical cancer. With unequal distribution of the vaccine, the racial disparity in cervical cancer may worsen,"said Dr. Lea Widdice, an assistant professor of pediatrics at the Cincinnati Children's Hospital Medical Center. Dr. Widdice presented her results in a poster.

Moreover, overall only 14% of girls initiating the HPV vaccine series actually completed the three-shot series within 7 months of the first dose. Clinical recommendations for the vaccine are to get the third shot 6 months after the first.

Dr. Widdice and her colleagues conducted a retrospective review of medical records on 3,297 girls between ages 9 and 26 years, and who received the first HPV vaccine dose between June 2006 and June 2008 from an urban, academic, pediatric medical center with multiple primary care and specialty clinics.

Overall, 11% of the black girls received all three doses of the vaccine, compared with 22% of the white girls and 15% of those identified as other races. Patients were predominately from primary care (95%) and 65% used Medicaid. The majority (67%) self-identified as black, 29% said they were white, and 4% were classified as other races.

Race was still associated with getting all three doses on schedule even after controlling for type of insurance and the different clinics giving the vaccine. ■

EPIDUO™ **Rx only**
(adapalene and benzoyl peroxide) Gel 0.1% / 2.5%
For Topical Use Only
Not For Ophthalmic, Oral, or Intravaginal Use.
BRIEF SUMMARY

INDICATIONS AND USAGE
EPIDUO Gel is a combination of adapalene, a retinoid, and benzoyl peroxide, and is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Ultraviolet Light and Environmental Exposure: Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided.
Erythema, scaling, dryness, and stinging/burning may occur with use of EPIDUO Gel.

ADVERSE REACTIONS
Observed local adverse reactions in patients treated with EPIDUO Gel were erythema, scaling, dryness, stinging, and burning. Other most commonly reported adverse events (≥1%) in patients treated with EPIDUO Gel were dry skin, contact dermatitis, application site burning, application site irritation, skin irritation.

DRUG INTERACTIONS
Exercise caution in using preparations containing sulfur, resorcinol, or salicylic acid, medicated or abrasive soaps and cleansers and products with high concentrations of alcohol or astringents in combination with EPIDUO Gel. Concomitant use of topical products with a strong drying effect can increase irritation. Use with caution.

Pregnancy
Pregnancy Category C. There are no well-controlled trials in pregnant women treated with EPIDUO Gel. Animal reproduction studies have not been conducted with the combination gel or benzoyl peroxide. Furthermore, such studies are not always predictive of human response; therefore, EPIDUO Gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus.
No teratogenic effects were observed in rats treated with oral doses of 0.15 to 5.0 mg adapalene/kg/day, up to 25 times (mg/m^2/day) the maximum recommended human dose (MRHD) of 2 grams of EPIDUO Gel. However, teratogenic changes were observed in rats and rabbits when treated with oral doses of ≥ 25 mg adapalene/kg/day representing 123 and 246 times MRHD, respectively. Findings included cleft palate, microphthalmia, encephalocele and skeletal abnormalities in rats; and umbilical hernia, exophthalmos and kidney and skeletal abnormalities in rabbits.
Dermal teratology studies conducted in rats and rabbits at doses of 0.6-6.0 mg adapalene/kg/day [25-59 times (mg/m^2) the MRHD] exhibited no fetotoxicity and only minimal increases in supernumerary ribs in both species and delayed ossification in rabbits.

Nursing Mothers
It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of EPIDUO Gel. Because many drugs are excreted in human milk, caution should be exercised when EPIDUO Gel is administered to a nursing woman.

Pediatric Use
Safety and effectiveness of EPIDUO Gel in pediatric patients under the age of 12 have not been established.

Geriatric Use
Clinical studies of EPIDUO Gel did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No carcinogenicity, photocarcinogenicity, genotoxicity, or fertility studies were conducted with EPIDUO Gel.
Carcinogenicity studies with adapalene have been conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day (1.2, 3.9, and 12 mg/m^2/day), and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day (0.9, 3.0, and 9.0 mg/m^2/day). In terms of body surface area, the highest dose levels are 9.8 (mice) and 7.4 times (rats) the MRHD of 2 grams of EPIDUO Gel. In the rat study, an increased incidence of benign and malignant pheochromcytomas in the adrenal medulla of male rats was observed.
No significant increase in tumor formation was observed in rodents topically treated with 15-25% benzoyl peroxide carbopol gel (6-10 times the concentration of benzoyl peroxide in EPIDUO Gel) for two years. Rats received maximum daily applications of 138 (males) and 205 (females) mg benzoyl peroxide/kg. In terms of body surface area, these levels are 27-40 times the MRHD. Similar results were obtained in mice topically treated with 25% benzoyl peroxide carbopol gel for 56 weeks followed by intermittent treatment with 15% benzoyl peroxide carbopol gel for rest of the 2 years study period, and in mice topically treated with 5% benzoyl peroxide carbopol gel for two years.
The role of benzoyl peroxide as a tumor promoter has been well established in several animal species. However, the significance of this finding in humans is unknown.
In a photocarcinogenicity study conducted with 5% benzoyl peroxide carbopol gel, no increase in UV-induced tumor formation was observed in hairless mice topically treated for 40 weeks.
No photocarcinogenicity studies were conducted with adapalene. However, animal studies have shown an increased tumorigenic risk with the use of pharmacologically similar drugs (e.g., retinoids) when exposed to UV irradiation in the laboratory or sunlight. Although the significance of these findings to humans is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial irradiation sources.
Adapalene did not exhibit mutagenic or genotoxic effects *in vitro* (Ames test, Chinese hamster ovary cell assay, mouse lymphoma TK assay) or *in vivo* (mouse micronucleus test).
Bacterial mutagenicity assays (Ames test) with benzoyl peroxide has provided mixed results, mutagenic potential was observed in a few but not in a majority of investigations. Benzoyl peroxide has been shown to produce single-strand DNA breaks in human bronchial epithelial and mouse epidermal cells, it has caused DNA-protein cross-links in the human cells, and has also induced a dose-dependent increase in sister chromatid exchanges in Chinese hamster ovary cells. In rat oral studies, 20 mg adapalene/kg/day (120 mg/m^2/day; 98 times the MRHD based on mg/m^2/day comparison) did not affect the reproductive performance and fertility of F_0 males and females, or growth, development and reproductive function of F_1 offspring.
No fertility studies were conducted with benzoyl peroxide.

PATIENT COUNSELING INFORMATION
– Advise patients to cleanse the area to be treated with a mild or soapless cleanser; pat dry. Apply EPIDUO Gel as a thin layer, avoiding the eyes, lips and mucous membranes.
– Advise patients not to use more than the recommended amount and not to apply more than once daily as this will not produce faster results, but may increase irritation.
– EPIDUO Gel may cause irritation such as erythema, scaling, dryness, stinging or burning.
– Advise patients to minimize exposure to sunlight, including sunlamps. Recommend the use of sunscreen products and protective apparel, (e.g., hat) when exposure cannot be avoided.
– EPIDUO Gel may bleach hair and colored fabric.

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Reference: 1. Gollnick HPM, Draelos Z, Glenn MJ, et al; Adapalene–BPO Study Group. Adapalene–benzoyl peroxide, a unique fixed-dose combination topical gel for the treatment of acne vulgaris: a transatlantic, randomized, double-blind, controlled study in 1670 patients. *Br J Dermatol.* 2009;161(5):1180-1189.

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Parents Call Vaccine Safety Top Priority

FROM THE NATIONAL IMMUNIZATION CONFERENCE

ATLANTA — Vaccine safety is the most important consideration for parents in deciding whether their teens should receive recommended vaccines, a national survey of parents showed.

The 557 respondents came from Harris Poll Online's survey panel, and each identified himself or herself as being the parent of at least one child aged 11-17 years, Dr. Stanley Schaffer of the University of Rochester (N.Y.) reported in a poster.

Parents most commonly cited vaccine safety as their single most important consideration in deciding whether their children should be immunized. Concerns about potential side effects were most pronounced for the human papillomavirus (HPV) vaccine; it was cited by 66% of parents of girls aged 11-14 years and 63% of parents of girls aged 15-17 years.

"While parents consider a number of factors when deciding whether or not to have their adolescents immunized, vaccine safety is clearly their No. 1 concern," Dr. Schaffer said in an interview.

—Roxana Guilford-Blake

Disclosures: *None was reported.*