

Lack of HIV Testing Behind Minority Infection Rate

BY JOEL B. FINKELSTEIN
Contributing Writer

WASHINGTON — Widespread testing would likely blunt the high HIV infection rate among African Americans and Latinos, but little money and effort have been put into prevention, experts said at the National Minority Quality Forum's 2008 Leadership Summit.

"African Americans and Latinos suffer disproportionately from the HIV/AIDS

epidemic in this country," said Dr. Madeline Sutton, who helps lead the Heightened National Response to the HIV/AIDS Crisis Among African Americans, a program of the Centers for Disease Control and Prevention.

Dr. Sutton is the latest director of the \$45 million effort to expand the use of HIV testing; that effort has suffered from revolving leadership, however, and has so far not had overwhelming impact, according to the AIDS community.

"Test everyone and treat everyone. Those are probably the two things we can do right now," said Dr. John Bartlett, chief of the division of infectious diseases at Johns Hopkins University, Baltimore.

An HIV test costs approximately \$15, which is relatively inexpensive, Dr. Bartlett said, pointing out that it is highly accurate and detects a disease that is lethal if not treated and manageable when it is.

It's a "dream test," yet it's not being used, he said at a meeting sponsored by

the Alliance of Minority Medical Associations, the National Association for Equal Opportunity in Higher Education, and the Department of Health and Human Services.

That the test is underused translates to more transmission. The rate of infection is four- to fivefold higher among individuals who don't know they have the disease. Currently, 40% of the people who test positive for HIV have had the infection for 8-10 years, he noted.

Minorities face obstacles that researchers are still struggling to identify. For African Americans, it's not clearly genetics or behavior that is leading to the explosion in the infection rate, Dr. Sutton said. In part, the CDC's effort is based on forming a better understanding of what

the barriers are to testing.

"A lot of issues have to do with stigma and how we get people to the next level," she said.

Latino patients face the same barriers and more, given the inherent stigma created by the immi-

gration debate, said Britt Rios-Ellis, Ph.D., director of the Center for Latino Community Health, Evaluation, and Leadership Training, a partnership between the National Council of La Raza and California State University, Long Beach.

"Latinos are the only minority group to see a doubling of HIV infection due to heterosexual contact, from 5% to 12% for males and from 23% to 67% for females between 2001 and 2006. And research in rural Mexico is indicating that most of the women who have AIDS there are married. We're seeing the same pattern here," she said.

For both Latinos and African Americans, the message is the same: By getting tested and treated, they can do something not only for their families and their communities, but for themselves as well.

"We see that 86% of our [federal] dollars have been spent on biomedical solutions, and those people who are receiving testing and care are doing very, very well. If we could get everyone into testing and care, we know that we would make a difference," Dr. Rios-Ellis said. ■

Clindagel® (clindamycin phosphate gel) topical gel, 1%

Rx only

Brief Summary

For External Use

INDICATIONS AND USAGE: Clindagel® is indicated for topical application in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate. (See CONTRAINDICATIONS, WARNINGS, and ADVERSE REACTIONS.)

CONTRAINDICATIONS: Clindagel® is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

WARNINGS: Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in patient death. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

Studies indicate a toxin(s) produced by *Clostridia* is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis. Stool culture for *Clostridium difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.

When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea. Antiperistaltic agents, such as opiates and diphenoxylate with atropine, may prolong and/or worsen the condition.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.

PRECAUTIONS

General: Clindagel® should be prescribed with caution in atopic individuals.

Drug Interactions: Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenicity of a 1% clindamycin phosphate gel similar to Clindagel® was evaluated by daily application to mice for two years. The daily doses used in this study were approximately 3 and 15 times higher than the human dose of clindamycin phosphate from 5 milliliters of Clindagel®, assuming complete absorption and based on a body surface area comparison. No significant increase in tumors was noted in the treated animals. A 1% clindamycin phosphate gel similar to Clindagel® caused a statistically significant shortening of the median time to tumor onset in a study in hairless mice in which tumors were induced by exposure to simulated sunlight.

Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative. Reproduction studies in rats using oral doses of clindamycin hydrochloride and clindamycin palmitate hydrochloride have revealed no evidence of impaired fertility.

Pregnancy: Teratogenic effects—Pregnancy Category B

Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin phosphate, clindamycin hydrochloride and clindamycin palmitate hydrochloride. These studies revealed no evidence of fetal harm. The highest dose used in the rat and mouse teratogenicity studies was

equivalent to a clindamycin phosphate dose of 432 mg/kg. For a rat, this dose is 84 fold higher and for a mouse 42 fold higher, than the anticipated human dose of clindamycin phosphate from Clindagel® based on a mg/m² comparison. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether clindamycin is excreted in human milk following use of Clindagel®. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children under the age of 12 have not been established.

Geriatric Use: The clinical study with Clindagel® did not include sufficient numbers of patients aged 65 and over to determine if they respond differently than younger patients.

ADVERSE REACTIONS: In the one well-controlled clinical study comparing Clindagel® and its vehicle, the incidence of skin and appendages adverse events occurring in ≥1% of the patients in either group is presented below:

Body System/Adverse Event	Number (%) of Patients	
	Clindagel® QD N=168	Vehicle Gel QD N=84
Skin and appendages disorders		
Dermatitis	0 (0.0)	1 (1.2)
Dermatitis contact	0 (0.0)	1 (1.2)
Dermatitis fungal	0 (0.0)	1 (1.2)
Folliculitis	0 (0.0)	1 (1.2)
Photosensitivity reaction	0 (0.0)	1 (1.2)
Pruritus	1 (0.6)	1 (1.2)
Rash erythematous	0 (0.0)	0 (0.0)
Skin dry	0 (0.0)	0 (0.0)
Peeling	1 (0.6)	0 (0.0)

Orally and parenterally administered clindamycin has been associated with severe colitis, which may end fatally.

Cases of diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported as adverse reactions in patients treated with oral and parenteral formulations of clindamycin and rarely with topical clindamycin (see WARNINGS). Abdominal pain and gastrointestinal disturbances, as well as gram-negative folliculitis, have also been reported in association with the use of topical formulations of clindamycin.

OVERDOSE: Topically applied Clindagel® may be absorbed in sufficient amounts to produce systemic effects (see WARNINGS).

Reference: 1. Shalita AR, Myers JA, Krochmal L, Yaroshinsky A. The safety and efficacy of clindamycin phosphate foam 1% versus clindamycin phosphate topical gel 1% for the treatment of acne vulgaris. *J Drugs Dermatol.* 2005;4(1):48-56.

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Resource on Health Care Innovations

The Agency for Healthcare Research and Quality has launched a new Web resource called the Health Care Innovations Exchange to share examples of both successful and unsuccessful attempts at innovation in health care. It initially is starting out with 100 examples and will be updated every 2 weeks. For more information, visit www.innovations.ahrq.gov. ■