HIV Notification, Counseling Soar With Rapid HIV Testing

BY PATRICE WENDLING
Chicago Bureau

QUEBEC CITY — The use of rapid human immunodeficiency virus testing has had a profound impact on primary care settings in New Jersey, Denise Young, M.D., reported in a poster at the annual meeting of the North American Primary Care Research Group.

Because the test doesn't require patients to make a second visit to receive their results, more HIV-positive patients are learning of their HIV status and receiving counseling.

New Jersey, which is fifth in the United States in cumulative reported AIDS cases and first in the proportion of women living with AIDS, introduced rapid HIV testing at publicly funded testing and counseling clinics in November 2003. It is now used in 90 sites throughout the state.

Testing has been done with the OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Bethlehem, Pa.), which is approved by the Food and Drug Administration for use with whole blood. It is not approved for serum testing or stored samples.

A whole-blood specimen is obtained via fingerstick or venipuncture and inserted into the testing device, which resembles a home pregnancy test kit. Results are ready in 20 minutes.

This compares with 1-2 weeks for the most commonly used initial HIV test, the enzyme immune assay, confirmed with Western blot or immunofluorescence assay.

Prior to rapid testing, only 65% of patients in New Jersey returned for their results.

In contrast, 99.7% of 25,264 patients screened with rapid HIV testing got their results and received counseling, according to an analysis of state databases through July 21, 2005.

A total of 510 (2%) patients were HIV positive. Of these, 327 (64%) were newly diagnosed, reported Dr. Young, Robert Wood Johnson Medical School, New Brunswick, N.J., and her associates.

Further analysis will determine if the seroprevalence at rapid test sites is the same as at traditional testing sites, or if newly diagnosed patients are getting into treatment services in a timely manner, she said.

It's hoped that by providing the opportunity to engage patients more quickly, the test will help decrease the mortality and morbidity associated with HIV infection.

Rapid testing is also being looked at as a way to lessen racial disparities that currently exist in New Jersey, which has one of the highest HIV infection rates in the nation, she said.

One in every 66 African Americans and 1 in every 171 Hispanics in New Jersey is living with HIV/AIDS, according the New Jersey Department of Health and Senior Services.

The state health department encourages the use of rapid testing for occupational exposures and in pregnant women to reduce the risk of mother-to-child transmission, according to statements from the department. But there are trade-offs. More HIV-positive people will get their results. But some people will receive a false-positive result.

Postmarketing surveillance on the OraQuick test initiated by the Centers for Disease Control and Prevention in September 2003 has identified at least five HIV-infected patients who were incorrectly informed that their rapid HIV test results were positive, according to the CDC's Web site.

Publicly funded sites in New Jersey follow CDC protocol, which recommends that all preliminary positive results with rapid HIV testing be confirmed by Western blot or immunofluorescence assay, Dr. Young said. ■

FDA Proposes Changes To Condom Labels

BY MARY ELLEN SCHNEIDER
Senior Writer

New guidance from the Food and Drug Administration proposes that latex condom labels inform users that condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of contracting or spreading HIV or other sexually transmitted diseases.

The draft guidance from FDA, which is nonbinding, also recommends that the package insert for latex condoms say that condoms cannot protect against STDs such as human papilloma virus (HPV) and genital herpes when they are spread through contact with infected skin outside the area covered by the condom.

The draft guidance also includes statements that nonoxynol-9 could irritate the vagina and rectum and therefore may increase the risk of acquiring HIV/AIDS from an infected partner.

The proposed guidance is the result of a 5-year-old law that directs the FDA to ensure that condom labels are medically accurate, specifically in regard to their overall effectiveness in preventing STDs.

But the original congressional supporters of the provision—Sen. Tom Coburn (R-Okla.) and Rep. Mark Souder (R-Ind.)—are not completely satisfied with the FDA's conclusions.

"This is a step in the right direction," Rep. Souder said in a statement. "Inasmuch as the new label recommendations finally acknowledge that condoms will not protect against some STDs."

But he added that he is discouraged that FDA's recommendation says that condom use may lower the risk of developing HPV-related diseases, such as genital warts and cancer.

"This dangerous assurance overlooks the fact that condoms will not protect a user from contracting or spreading the sexual disease to others," he said.

Reproductive health advocates, on the other hand, say that FDA officials did their best to produce evidence-based guidance in the context of political pressure from social conservatives who want to undermine public confidence in condoms.

But the FDA should continue to make improvements to the guidance, Vanessa Cullins, M.D., vice president for medical affairs at the Planned Parenthood Federation of America said in an interview.

It's important for the labeling to include a statement saying that condoms are the best protection against STDs for sexually active individuals, she said. This information is crucial to provide the necessary context to all the information that FDA is trying to convey, she said. ■

The FDA draft guidance is available online at www.fda.gov/cdrh/comp/guidance/1548.html.

Vaginal Flora May Affect Sexual, Perinatal HIV Transmission

BY SHARON WORCESTER
Southeast Bureau

CHARLESTON, S.C. — Certain vaginal isolates may affect the quantity of HIV RNA in cervicovaginal lavage, Jane Hitti, M.D., reported at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology.

Factors affecting the HIV RNA concentrations are important, because genital viral load is a major determinant of sexual and perinatal HIV transmission, noted Dr. Hitti of the University of Washington, Seattle.

She reported on 38 HIV-positive women who completed 163 study visits. Vaginal cultures, cervicovaginal lavage, and plasma were collected at each visit for HIV RNA quantitation.

Hydrogen peroxide–producing lactobacilli were associated with a significant decrease in cervicovaginal lavage HIV RNA concentrations, and *Trichomonas vaginalis*, *Prevotella bivia*, *Mycoplasma hominis*, and other anaerobes were associated with increases in cervicovaginal lavage HIV RNA concentrations.

Of 163 CVL samples, 95 had detectable HIV RNA, and the levels correlated significantly with plasma HIV RNA levels, she said.

After adjustment for log plasma HIV RNA, the log difference in cervicovaginal lavage HIV RNA was significant for H_2O_2 lactobacillus and *T. vaginalis*. Increased cervicovaginal lavage HIV RNA concentrations also were associated, although not significantly, with *M. hominis*, *P. bivia*, black gram-negative rods, *Candida albicans*, and bacterial vaginosis or intermediate flora.

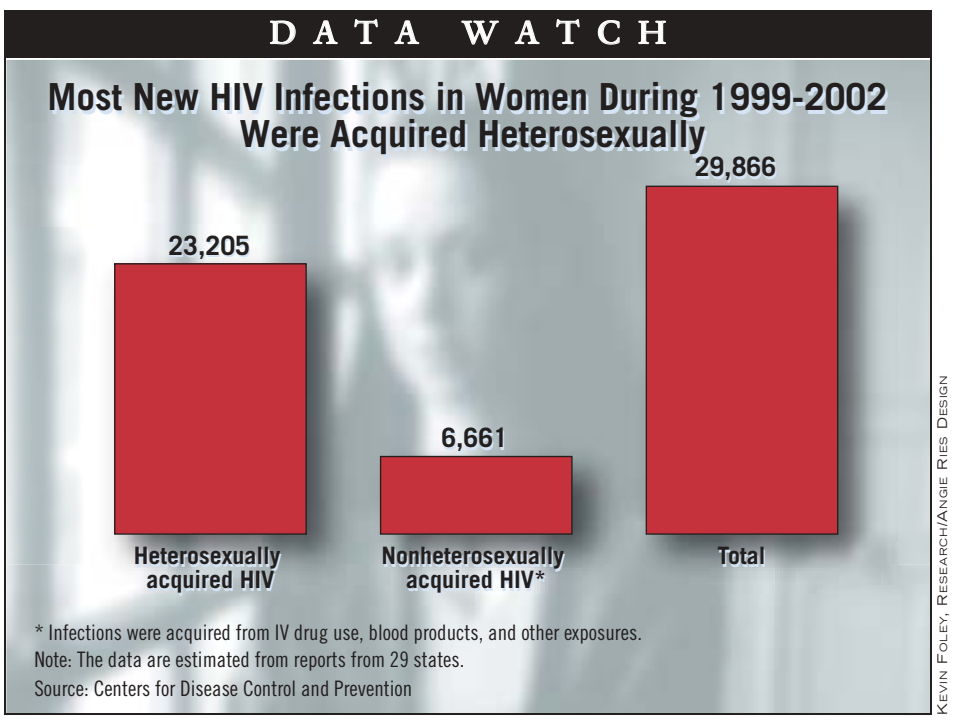
Also, cervicovaginal lavage HIV RNA concentrations were increased with higher vaginal concentrations of IL-8 in this study, Dr. Hitti noted.

Several vaginal isolates appear to directly influence cervicovaginal lavage viral load, and the effects appear to be independent of plasma viral load, she concluded, noting that an antibiotic treatment trial is underway to determine whether treatment for bacterial vaginosis and associated infections will decrease genital viral load.

"A very logical next step would be looking at ways to augment endogenous lactobacilli and looking at what effects that has," she said.

The prevalence of H_2O_2-producing lactobacilli is lower than what has been reported among HIV-negative women, even in the presence of bacterial vaginosis, she explained. ■

DATA WATCH



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