

PROFESSION

At-home HIV test could expand screening, hinder follow-up care

A private, immediate testing option might help stem transmission, but some physicians say that without in-person counseling patients could delay treatment.

By KEVIN B. O'REILLY, amednews staff. Posted June 4, 2012.

A Food and Drug Administration advisory panel is recommending approval of an over-the-counter, rapid at-home HIV test that would let patients take control of determining their HIV status and could expand the rate of testing.

But some physicians and public health experts say the product, the OraQuick In-Home HIV Test, would allow patients to skip pre- and post-test counseling. It also could hinder efforts to educate patients about practicing safe sex and starting treatment, they said.

About 240,000 Americans are infected with HIV and do not know it, according to estimates by the Centers for Disease Control and Prevention. Experts say these patients are the principal vector for HIV, so making it easier for people to learn their HIV status could help limit the disease's spread.

In 2006, the CDC recommended that all patients be offered an HIV test as a routine matter. Yet logistical, financial and legal obstacles have hampered this universal screening approach. And studies have found that when testing is routinely offered in emergency departments and other settings, patients frequently turn it down.

So could the at-home test — administered by swabbing the gums and inserting the vial into a solution, yielding a result in 20 to 40 minutes — help make a populationwide dent in detecting HIV? An FDA review presented at a May 15 meeting of the Blood Products Advisory Committee estimated that use of the at-home test among heterosexuals, injection drug users and men who have had sex with other men would yield 45,000 new positive test results and prevent more than 4,000 HIV transmissions a year.

The FDA also estimated that the test would yield 3,800 false negative results and 1,100 false positives a year. That figure concerns Arthur J. Ammann, MD, president of Global Strategies for HIV Prevention in Albany, Calif. The organization works to address international inequities in HIV prevention and treatment.

"That's too high," Dr. Ammann said. "A false negative may encourage increased sexual risk-taking. ... The thing that upsets me most is the test really removes the very point where you need to have that one-on-one counseling you need the most. You should be having protected sex. You need to let all your partners know."

The product's manufacturer, Bethlehem, Pa.-based OraSure Technologies, says it will provide 24-hour phone support through a toll-free number listed prominently on the packaging to help patients administer the test, interpret the results and get any follow-up care they need. Company officials say the phone support staff will receive 160 hours of training to answer patient questions and direct them to resources. They will stay on the line until patients are connected with someone at a physician's office or other treatment center during business hours.

Connecting patients to care

Phone support may not be enough for some patients who test positive but fail to follow through and seek proper counseling and medical care, said Donna Sweet, MD, an HIV specialist and professor of internal medicine at the Kansas University School of Medicine in Wichita.

"Do I worry about people burying this [HIV-positive] knowledge and hurting others? Yes, I do," Dr. Sweet said. "The most important part of testing is the linkage to care. That's where I worry there could be a problem. We won't know until we try it. It's a matter of getting it on the market and educating people as best as we can and making sure there are adequate and appropriate places for them to get care."

The FDA is expected to issue an approval decision this year on the product, which would be available over-the-counter to patients 17 and older.

The cost of the product — "significantly less" than \$60, but not yet finalized, according to OraSure — means that the most likely users will be low-risk "worried well" patients, said A. David Paltiel, PhD, professor of public health and management at Yale University School of Public Health in Connecticut. With fairly low baseline prevalence of HIV among this group of patients, the risk of false positives will rise, he predicted.

"This thing is like my grandmother's chicken soup. It's not going to hurt, but it's not going to do much good, either," said Paltiel, who has researched the cost-effectiveness of HIV/AIDS testing, prevention and treatment options.

Many other physicians and advocates for patients with HIV are optimistic that the product will be a useful option for those who want to avoid the stigma of getting tested at a clinic or who want a fast way to test themselves frequently.

"If it does help some people — though I think it will be a minority of the population — get tested sooner, then in that respect

it's a good thing," said James M. Sosman, MD, medical director of the HIV program at the University of Wisconsin in Madison. "Whatever we can do to lower the barrier to people getting tested is probably the most important thing."

ADDITIONAL INFORMATION:**WEBLINK**

Summary of safety and effectiveness of proposed OraQuick In-Home HIV Test, presented at Food and Drug Administration Blood Products Advisory Committee meeting, May 15

(www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM303657.pdf)

"Final Advisory Committee Briefing Materials," OraSure Technologies, May 15

(www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM303652.pdf)

"HIV Screenings in Health Care Settings: Some Progress, Even More Questions," *The Journal of the American Medical Association*, July 21, 2010 (jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2010.996)

"HIV in the United States: At a Glance," Centers for Disease Control and Prevention, March 14

(www.cdc.gov/hiv/resources/factsheets/us.htm)

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