Recommendation of HIV test brings diagnostic dilemma home

Last month, patient advocates hailed the unanimous vote by an advisory committee to the US Food and Drug Administration that recommended that the agency approve the OraQuick In-Home HIV test, an over-the-counter diagnostic that can be taken without medical supervision. If approved, the OraQuick test would be the first home test approved for an infectious disease. But concerns remain about whether the price will render it out of reach of those who need it most and what the test will mean for the handful of individuals participating in HIV vaccine trials.

The OraQuick test, from Pennsylvania-based OraSure Technologies, is a home version of a rapid HIV test already used in many medical centers. The kit includes an instructional booklet and a test stick, which the user swipes along his or her upper and lower gums and contains molecules that react against HIV-specific antibodies produced by the body. Results are ready just 20 minutes later. Two lines on the dipstick signify a positive result, which must be confirmed by a more sensitive test at a clinical laboratory. The company plans to provide a 24-hour hotline so that customers can ask questions or receive counseling, but the phone call is optional.

FDA approval of OraQuick would probably pave the way for other in-home HIV tests. Chembio Diagnostic Systems, based just outside New York City, already plans to seek approval for a home version of its rapid 'Sure Check HIV' test, which requires a drop of blood. Although over-the-counter tests for HIV and hepatitis C are already available from Illinois-based Home Access Health Corporation, both require the consumer to send a blood specimen to a laboratory for analysis and results.

No test is perfect, however, and one major concern is that people who test negative using the OraQuick kit might actually have HIV. In a recent phase 3 trial, OraSure gave the prototype to 5,662 individuals to use in their homes. The results, made public by the company in filing for approval, indicate that only 93% of the 114 individuals infected with HIV received a positive test result. In the clinical setting, the same test is 99% accurate. Why the home test missed so many infections isn't clear. Because the OraQuick test detects HIV-specific antibodies, recently infected individuals may test negative. False positives seemed to be less of a problem; only one uninfected study participant tested positive.

Despite the concern, the committee decided to support the test. "We shouldn't let the perfect be the enemy of the good," J. Brooks

A premium for privacy: Cost might dissuade some from taking the at-home test for HIV.

Jackson, a committee member and director of pathology at the Johns Hopkins University School of Medicine in Baltimore, said at the FDA advisory committee meeting on 15 May. However, committee members did suggest several changes to the language in the test kit. For example, Susan Buchbinder, a committee member and HIV researcher at the University of California, San Francisco, urged OraSure to clearly state that individuals who have been involved in an HIV vaccine trial should not take the test. A 2010 study found that 42% of HIV vaccine trial participants tested positive for the virus even though they were uninfected, as immunization prompts certain antibodies that are picked up by diagnostics (*JAMA* 304, 275–283, 2010). Some in the AIDS research community have also noted that the in-home test could jeopardize the scientific integrity of such vaccine trials by making it easier for participants to determine whether they have received the vaccine or a placebo.

Dollars and sense

OraSure expects the FDA to make a decision in the coming months, although no formal timeline has been set. The agency isn't required to follow an advisory committee's recommendation, but it typically does. Ultimately, the extent to which OraQuick will improve public health hinges on whether high-risk groups buy the test. An FDA analysis presented at the committee meeting found that, if one in every 100 Americans uses the test, OraQuick could newly identify up to 45,000 HIV-positive individuals and prevent

around 4,000 new infections in the country each year.

Yet OraQuick's popularity will depend in part on its price. Preliminary results from a University of Washington School of Public Health study presented at the 2012 Conference on Retroviruses and Opportunistic Infections suggest that price is crucial. Of 108 surveyed men who have sex with men in Seattle, 13% said they would only take the test if it was free, and another 45% reported that they wouldn't pay more than \$20.

OraSure currently sells the test to clinics for \$17.50, but the version sold directly to consumers for home testing is likely to be more expensive (although the company has not yet given details). At the committee meeting, Stephen Lee, OraSure's chief scientific officer, noted that the price will be "substantially lower" than the price of Home Access's HIV test, which he said retails for about \$60.

David Paltiel, a public health researcher at the Yale University School of Medicine in New Haven, Connecticut, points out that individuals with the highest risk of HIV tend to be in the lowest income brackets, and OraQuick may cost more than they are willing to pay. So he expects its consumers will probably be well-off individuals "composed disproportionately of HIV-uninfected, 'worried well' persons and very recently infected, undetectable cases."

The availability of an in-home test "is not going to hurt," Paltiel says, stressing the benefit to individuals. "But I don't think it's going to help" from a public health standpoint, he notes.

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