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Home HIV Testing: Good News but Not a Game Changer

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On 3 July 2012, the U.S. Food and Drug Administration (FDA) approved the OraQuick In-Home HIV Test (OraSure Technologies, Bethlehem, Pennsylvania) to detect antibodies to HIV types 1 and 2. This test will soon be available for sale both online and at more than 30 000 retail outlets nationwide. This is the first truly over-the-counter home HIV testing kit, the same test that professionals have used in health care and community-based settings since its approval in 2004. The test provides simple, accurate, in-home detection of HIV infection in 20 minutes using an oral fluid sample (1, 2).

Public response to the FDA announcement was swift and overwhelmingly enthusiastic. Supporters labeled the approval decision a victory for personal empowerment (3). National authorities predicted that OraQuick would eliminate the stigma and inconvenience of HIV testing in professional settings, remove barriers to lifesaving care, and help bring the domestic AIDS epidemic under control (4).

Our reaction is more tempered. On balance, we applaud the FDA's decision to promote healthy sexual behaviors by making HIV tests more available and more convenient. However, we doubt that OraQuick will have much effect in either lowering barriers to care or reducing HIV transmission. A \$40 home HIV test is not even likely to make an appreciable dent in the number of undetected HIV infections; rather, it will attract a predominantly affluent clientele composed of persons at low risk for HIV infection (the "worried well" and new sexual partners), persons with very recent (and therefore undetectable) high-risk exposures, and persons with known HIV infection seeking to monitor therapy or to pursue a misperception that treatment has reversed their seropositivity (5–7). We offer the following cautious suggestions to providers when counseling their patients about the use, misuse, and anticipated benefits of home HIV testing.

Home Testing Is Not a Substitute for Routine HIV Screening in Health Care Settings

The U.S. Centers for Disease Control and Prevention recommends that all sexually active adults in the United States be tested at least once for HIV. Persons known to be at higher risk for infection should be tested more frequently (8). The availability of an over-the-counter, home-based HIV testing alternative does not alter the importance of this recommendation.

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The Centers for Disease Control and Prevention guidelines are based on an overwhelming body of scientific evidence showing that early HIV detection and linkage to care are effective, cost-effective, and best implemented in settings where high-quality testing and referral services can easily be provided, under 1 roof, to persons at risk for unidentified infection. Physicians still have a duty to promote HIV screening and to discuss strategies for HIV harm reduction with their sexually active patients. In cases where patients initiate the conversation with, “Should I use the home HIV test?” the provider’s first response should still be to offer an on-site test and to remind patients that provider-based testing is not only their cheapest alternative but also their most direct route to subsequent counseling and support.

Home Testing May Play an Appropriate Role in Support of Responsible Sexual Health Habits

Patients who know their current HIV status and are about to begin a sexual relationship with a new partner may be encouraged to obtain a home HIV test as 1 component of a comprehensive 3-way conversation (with partners and providers) covering such topics as shared risks, harm reduction, monogamy, birth control, and prevention of other sexually transmitted infections.

The following points may help prepare patients to anticipate and interpret home test results. First, the test does not detect the virus; it detects the body’s immune (antibody) response to that virus. Most people develop detectable antibodies within 6 weeks of infection; 97% respond within 3 months (1). Conservatively speaking, a result obtained today is only a reliable indicator of one’s HIV status 3 months ago (the so-called “window period”). Second, a negative result does not imply reduced susceptibility to infection and is certainly not a green light to take greater sexual risks in the future. Third, a positive (“reactive”) result requires immediate confirmation using a test that is not available for home use. Patients should contact a health provider immediately; present themselves in person; call an HIV hotline; or use OraSure’s 24-hours-per-day, 7-days-per-week toll-free customer support center (1).

Home Testing May Play a Limited Role as an Alternative to HIV Screening in Professional Settings

Any number of personal considerations may discourage patients from accepting their provider’s offer of an on-the-spot HIV test: fear, stigma, mistrust of the health system, confidentiality concerns, or inadequate time to mull over the decision. For patients who opt out, home testing may serve as an alternative strategy. Because patients may balk on discovering the retail price of the home test, providers should emphasize that the offer of an on-site option stands.

Home Testing Is Not an Appropriate Means of Assessing the Risks of a Very Recent Exposure

Some patients may be drawn to home testing to allay fears after a risky sexual encounter or other exposure event. Providers should describe the window period and explain why antibody tests reveal nothing about infections that may have occurred in the past few days. These patients should be encouraged to obtain 2 sequential HIV antibody tests, preferably in a professional setting: the first immediately, to obtain baseline information about their HIV status before the exposure event, and the second in 6 weeks.

For patients with symptoms of a viral syndrome after a recent exposure, the work-up should include a full panel of HIV tests, including a test for HIV RNA to detect acute HIV infection. Until the cause of these symptoms is resolved, symptomatic patients should be strongly discouraged from sexual or high-risk activity; if primary HIV infection is the cause, these patients will be maximally infectious during this period.

Patients Who Present With a Home Test Result in Hand Require Particular Sensitivity

Until now, we have discussed the situation where the patient inquires prospectively about the purchase of a home HIV test. A more probable scenario is that patients will present after the fact, with the results of a home test in hand. Patients who report a negative result should be reminded that this reveals nothing about very recent exposures and that, if they have been at consistently high risk, negative results probably reflect good fortune more than any immunity from infection. For patients who report histories of particularly high risk-taking, it may also be important to consider the possibility of false-negative results. The OraQuick home test has an estimated 92% sensitivity, meaning that 1 in 12 people who have HIV infection will nevertheless receive a negative test result (1). When a false-negative result is suspected, a second screening—preferably one that tests for HIV RNA—should be obtained.

All positive (reactive) home test results should be viewed as preliminary findings requiring verification. Confirmation has traditionally included both a repeat enzyme immunoassay and a Western blot test; however, a growing body of evidence supports the shift to confirmation using fourth-generation tests that can detect both p24 antigen and conventional HIV antibodies (9). Because reactive home test results will be rare, we also recommend obtaining a CD4 cell count and an HIV RNA test: If the home test proves to be a false-positive, the additional tests will provide further reassurance; if the positive home test result is confirmed, they will provide information for disease staging and baseline prognostic markers.

These patients—who have newly self-identified through home testing—may be among the most refractory to care, the most skeptical of the health system, and the most worried about stigma and privacy. They will require a disproportionate degree of time, reassurance, and resources. For example, they will need to be referred to a social worker or case manager who can assist with anticipated issues of emotional or personal chaos, disclosure of the diagnosis to loved ones, pharmacy insurance, and legal ramifications. They should also be referred to an HIV care provider—ideally within a week—because most general providers rely on this referral to stabilize the patient to the proper treatment regimen.

Summary

We are struck by the unreserved enthusiasm that the FDA's approval of OraQuick has prompted. We believe that home HIV testing may play a useful but limited part in a program of good sexual health. Expectations that it will eliminate barriers to expanded HIV detection seem unrealistic. Home HIV testing is not a substitute for routine HIV screening in health care settings, provision of which is still our best hope for identifying the 235 000 Americans who remain unaware of their HIV infection (10) and linking them to effective care.

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