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Rapid HIV Testing at Home: Does It Solve a Problem or Create One?

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The U.S. Food and Drug Administration (FDA) is considering approval of an over-the-counter, rapid HIV test for home use. To date, testimony presented before the FDA has been overwhelmingly supportive. Advocates have argued enthusiastically that there is value in empowering individuals to manage their HIV risks and have suggested that the availability of a rapid home HIV test will dramatically increase rates of disease detection in communities that have proven difficult to reach and to link to appropriate care. The authors offer a more cautious perspective. According to what is already known about the market demand for over-the-counter HIV testing kits, their costs, and the performance of rapid HIV tests in that market, the authors do not anticipate that the rapid home test will have a profound impact either on the HIV public health crisis or on the populations in greatest need. Home HIV testing will attract a predominantly affluent clientele, composed disproportionately of HIV-uninfected new couples and "worried well" persons, as well as very recently infected persons with undetectable disease. The authors illustrate how testing in these populations may have the perverse effect of increasing both false-positive and false-negative results. A poorly functioning home HIV test may thereby undermine confidence in the reliability of HIV testing more generally and weaken critical efforts to expand HIV detection and linkage to lifesaving care for the estimated 300 000 U.S. citizens with unidentified HIV infection.

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In November 2005, a U.S. Food and Drug Administration (FDA) advisory panel reviewed testimony regarding approval of OraQuick ADVANCE 1/2 (OraSure Technologies, Inc., Bethlehem, Pennsylvania), the first truly over-the-counter home HIV testing kit (1). The previous test, Home Access HIV-1 Test System (Home Access Health Corp., Hoffman Estates, Illinois), was approved in 1996 and was actually a home sample collection system. Results were available by telephone 3 days after a dried blood spot was submitted by mail. OraQuick provides accurate, private detection of infection with HIV-1 and HIV-2 in 20 minutes using a simple cheek swab. Public endorsement of home HIV testing has been overwhelmingly positive, a radical change from when the idea was first presented to the FDA in 1986 (1, 2). Supporters argue that OraQuick offers personal choice and empowerment, overcoming the principal barriers to identifying the approximately 300 000 U.S. citizens who remain unaware of their HIV infection (3). We believe that this enthusiasm should be tempered with caution.

Who Will Test at Home?

Preapproval studies of Home Access suggested that it would appeal most to young, high-risk, low-income, nonwhite men (4), a population with infrequent medical encounters and low HIV testing rates (5). However, abstract preferences elicited without reference to risk, circumstance, or price may not predict purchase decisions. We already know a great deal about who will and who will not test at home (6).

Those Who Can Afford It

Although 79% of persons negative for HIV infection report interest in a home HIV test, favorable responses drop to 40% when respondents are told that the test costs $40 (current Home Access price) (7). Most people with HIV infection will pay no more than $15 for a home HIV test (8), and the poor are substantially less likely to use it (9). Although OraQuick has not yet been priced for over-the-counter sales, it currently costs $11 to $17 per kit when purchased in high volume for research use (10–12). Additional retail markup will probably render the test inaccessible to vulnerable populations.

"Worried Well"

Expectations are that home tests will also appeal to those "who routinely get anxious, often for very little reason, about their partners or their past" (13). Indeed, the "worried well," with their frequent, repeatedly negative test results, are a fixture at public HIV testing centers (14). This population will emerge as a pillar of the customer base for home HIV testing.

New Couples

New partners may use the test to confirm each other's HIV status before initiating sexual relations. Home testing represents the most recent addition to the expanding armamentarium of technologies, including pregnancy tests and emergency contraception, to help people take charge of their sexual behavior. However, the degree of HIV risk in this market niche—and its overlap with the affluent and "worried well"—needs study. It is also unknown whether couples will be equally conscientious in their post-test sexual practices or if negative results will promote more disinhibited risk taking (13).

Persons with High-Risk Exposures

People with recent high-risk exposures may turn to the home HIV test after a night's sleep and a sobering realization of their high-risk activity. Home HIV test use may mirror that of emergency contraception or the in-

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Table. **Performance of Rapid HIV Tests under Alternative Population Prevalences and Seroconversion (Antibody-Positive) Levels***

Variable	HIV-Infected Persons, *n*	HIV-Uninfected Persons, *n*	Total, *n*	Positive Predictive Value	Negative Predictive Value
Population prevalence of 3.00%					
Positive test result	298	19	317	298/(298 + 19) = 94%	
Negative test result	2	9681	9 683		9681/(2 + 9681) = 100%
Total	300	9700	10 000		
Population prevalence of 0.20%					
Positive test result	20	20	40	20/(20 + 20) = 50%	
Negative test result	0	9960	9960		9960/(0 + 9960) = 100%
Total	20	9980	10 000		
Population prevalence of 0.20% (50% antibody-positive and 50% "window period")					
Positive test result	10	20	30	10/(10 + 20) = 33%	
Negative test result	10†	9960	9970		9960/(10 + 9960) = 99%
Total	20	9980	10 000		

*Values rounded to the nearest percentage.
†Percentage of all infections not detected = 10/(10 + 10) = 50%.

creased use of nonoccupational postexposure prophylaxis (15). The concern was voiced repeatedly at the FDA hearings that the expected clientele was widely thought to be "college binge drinkers" and those recovering from a "wild night" (1).

Persons Seeking Confirmation

Persons who know they are HIV-infected may also turn to home testing to monitor their therapy and confirm positive results obtained elsewhere. A study of Home Access noted that 12% of users who received positive test results were already receiving antiretroviral therapy; many used the home test to pursue the incorrect belief that treatment could reverse their seropositivity (16).

The Problem of False-Positive Results

The downside, if home HIV testing appeals disproportionately to those at low risk, is the erosion in public confidence created by a test that is perceived to function poorly. The predictive value of any diagnostic test is a function of 2 factors: its inherent accuracy and the disease prevalence in the population tested. With regard to inherent accuracy, the OraQuick test has a high sensitivity (99.3%) and specificity (99.8%), similar to previously approved home tests and standard HIV enzyme-linked immunosorbent assays performed in health care settings (12, 17, 18). These values are independent of the population in which the test is conducted. By contrast, the disease prevalence is inextricably linked to the question of who will test at home, and this has important implications for the test's predictive performance.

In a population with a 3% prevalence of unidentified HIV infection (the approximate HIV prevalence among injection drug users in New York City), 300 out of every 10 000 persons tested will truly have HIV infection (**Table**). The OraQuick will correctly identify all but 2 of these persons. It will also deliver false-positive (incorrect) test results to 19 of the 9700 uninfected persons because of imperfect specificity. The positive predictive value of the test in this setting is 94%. Only 6% of positive test results will prove to be mistaken on confirmation. Thus, in high-prevalence settings (for example, medical settings), false-positive results are a minor concern.

Using a more realistic 0.2% rate of unidentified HIV infection, the test will correctly identify all 20 true infections. However, it will deliver false-positive test results in 20 of the 9980 uninfected cases, and its predictive value will fall to 50%. One in every 2 patients receiving positive test results in this population will subsequently learn that the finding was an emotionally distressful false alarm.

The Problem of False-Negative Results

Like all HIV antibody tests, the home test will not detect HIV infection in the approximately 8-week "window period" between exposure and the development of HIV antibodies (19). The effects of substantial "morning after" testing on rates of failed case detection and on subsequent transmission behavior are poorly understood. Suppose if in the population earlier identified as having a 0.2% disease prevalence, 50% of those with actual infections test themselves during the "window period." Two thirds of the positive test results will be incorrect. Worse still, 50% of all actual infections will be missed (false-negative results). In instances of failed detection, the home OraQuick may convey a false sense of security and reinforce risky behaviors during one of the most infectious stages of HIV disease (20).

The Impact of Home Testing on Stigma and Linkage to Care

Although substantial effort has been expended to improve access to HIV testing, comparatively less attention has focused on linking identified patients to care to con-

firm preliminary results and initiate treatment (21–23). Home testing may exacerbate weaknesses in current approaches to linkage.

First, it is not clear if home HIV testing will increase or decrease the psychological barriers to care. A more convenient, private home kit may popularize HIV/AIDS testing and remove the stigma surrounding it. However, it may also increase stigma by making HIV testing a more clandestine activity. Persons most anxious to keep their HIV testing activities private may also prove to be those most refractory to counseling, confirmation, and linkage.

Second, it is not clear how the downstream performance of home testing will be evaluated. The long-term success of any HIV testing program should be measured not only by the number of persons tested or the proportion of HIV infections identified but also by the rate at which newly identified cases are linked to care (22). Because home testing results cannot be centrally reported, it will be difficult to compare confirmation and linkage rates of home testing with those of other screening approaches.

CONCLUSIONS

On balance, rapid home HIV testing makes good sense. There is value in empowering individuals to manage their HIV risks; in helping couples to learn their partners' HIV status before the initiation of sexual relations; and in addressing the 3 principal barriers to wider HIV test acceptance: stigma, convenience, and privacy. Rapid home testing may facilitate the detection of HIV infection in communities that have proven difficult to reach.

Contrary to the conventional view, however, we do not anticipate that OraQuick will have a profound impact, either on the HIV public health crisis or on the underserved populations in greatest need (16). Home HIV testing will attract a predominantly affluent clientele, composed disproportionately of HIV-uninfected, "worried well" persons and very recently infected persons with undetectable disease. This will have the perverse effect of increasing the proportion of false-positive and false-negative results, while making little appreciable dent in the size of the undetected HIV pool. False results erode public confidence in the reliability and the value of proven methods of HIV detection (24). Furthermore, wide availability of home testing may fuel the perception that HIV testing services are no longer needed in health care settings—a serious concern because the health care system remains the best venue in which to make new HIV diagnoses (21, 22, 25). The real issue is not the availability of another HIV test but the linking of persons with HIV infection to life-saving care (22). Finally, by removing HIV screening from the public venue, the home test may exacerbate the stigma of testing and further impede access to care for the people who need it most.

Some of our concerns would be assuaged if the home HIV test were priced to be accessible to those at highest risk. We optimistically note President George W. Bush's recent commitment to expand the delivery of rapid testing in disadvantaged communities (26). If some of the untoward consequences of selection effects and price discrimination are eliminated, an affordably priced home HIV test could provide partial over-the-counter relief for an ongoing public health crisis.

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