



Home Testing for HIV

Alexi A. Wright, M.D., and Ingrid T. Katz, M.D., M.H.S.

The Food and Drug Administration (FDA) has been struggling for nearly two decades over the possible approval of a do-it-yourself home test for human immunodeficiency virus (HIV). Now, after

years of politicking and lawsuits, it finally looks possible. Last November, after OraSure Technologies announced that it was seeking over-the-counter status for its rapid HIV-antibody test, the FDA convened a panel of experts to determine the requirements for approval of a home test. The OraQuick test, which is widely used in clinics, works like a home pregnancy test, except that it uses oral fluid instead of urine.

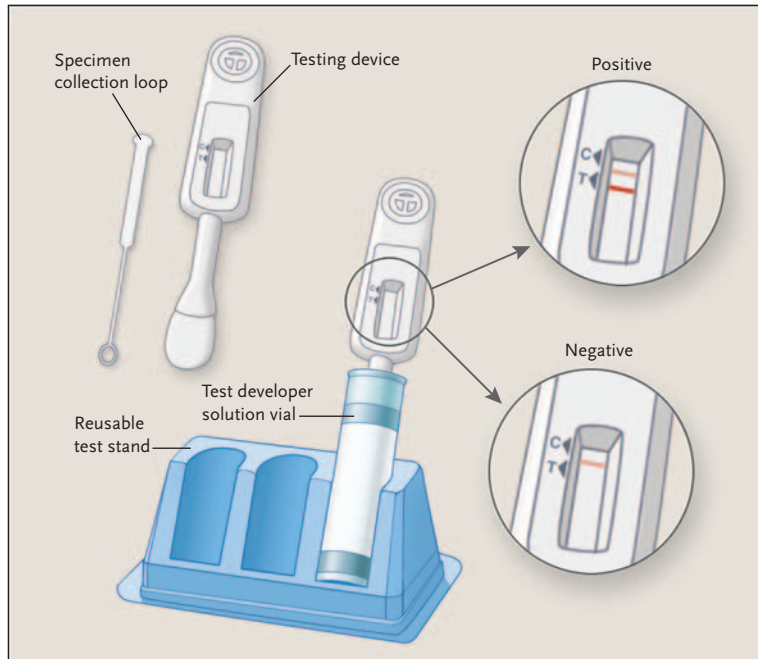
The November 2005 meeting, held in Gaithersburg, Maryland, was attended by an odd group of bedfellows — physicians, evangelists, gay activists, venture capitalists, and public health officials — who assembled to lobby the

Blood Products Advisory Committee about over-the-counter availability. Their arguments were as diverse as their backgrounds, but only 2 of the nearly 20 people who spoke voiced concern about bringing a home HIV test to market. The overwhelming majority argued that it is long overdue.

Tom Donahoe, a young AIDS activist and founder of Who's Positive, an HIV outreach and advocacy organization for young people, traveled from State College, Pennsylvania, to share his story at the hearings. Donahoe grew up in a rural town where, he says, gay men were surrounded by shame and stigma. As the eldest son in a military family, he was an un-

likely advocate for gay rights, but he became active in the gay community during his first year at Pennsylvania State University. When he decided to get tested for HIV, he avoided the only AIDS service organization in town, where many of his friends worked, opting instead for the anonymity of a new primary care doctor. One week later, he received a telephone call from the physician and knew instantly that he had tested positive. He recalled arriving at the doctor's office, where a faceless white coat entered the room, announced that he had HIV, and sent him home. "I left without any resources," Donahoe said. "I didn't have a single pamphlet or number for a crisis hotline. It was, like, here's the news, have a good day."

Donahoe's experience is an AIDS activist's worst nightmare. When the first HIV test was developed in 1985, activists lobbied



The OraQuick Rapid HIV-Antibody Test, Showing Positive and Negative Results.

for unique legislation to protect infected people from discrimination. In an unusual move, doctors were required to obtain specific permission before testing patients for an infectious disease. Many states mandated that health care providers offer face-to-face counseling before and after every HIV test to ensure that people who tested positive received support. There were also laws dictating how positive results were to be reported, which hampered the routine contact-tracing process. Many states did not allow HIV status to be included in the medical record.

In 1986, entrepreneur Elliott Millenson approached the FDA with plans to manufacture a test for home use. The skeptical agency deliberated for two years before declaring that testing should be restricted to health care professionals. Millenson filed a lawsuit against the FDA, which then held its first public hearings about home HIV tests in April 1989.

Venture capitalists were disappointed, however, when a powerful coalition — including several congressmen, the American Medical Association, the Centers for Disease Control and Prevention (CDC), and gay activists — objected to home tests, arguing that they might be inaccurate or increase the risk of suicide. AIDS activists reinforced the latter point by distributing copies of the obituary of a man who had jumped off the Golden Gate Bridge after learning that he was HIV-positive.

Those fears, however, were never realized. Over the next few years, as more HIV treatments became available, the FDA reversed its stance, and in 1996, it approved two home-collection kits for HIV, including one developed by Millenson. Both were available over the counter but required users to send their blood to a laboratory for HIV testing. Within a week, consumers could anonymously obtain their results and counseling by calling a toll-free telephone

number. Although some observers bemoaned the loss of face-to-face counseling, others argued that the home tests provided increased access and much-needed anonymity and privacy.

The FDA's approval of the kits meant that anonymous HIV testing was suddenly available nationwide, even in states where it was illegal. Several states tried to block sales, citing laws that mandated reporting the names of HIV-infected persons. The FDA responded that its approval trumped state laws, and the tests were launched.

Within a year, more than 175,000 people purchased kits, and the expanded screening was not associated with any reported increase in the rate of suicide.¹ This was welcome news to public health officials, who were concerned about waning vigilance regarding HIV prevention after the advent of antiretroviral therapies. They were encouraged by studies showing that HIV-positive persons modify their behavior by engaging in fewer high-risk sexual encounters after learning their serologic status²; thus, expanded testing should decrease HIV transmission and permit increased access of infected persons to effective therapies.

Unfortunately, an estimated 25 percent of HIV-positive Americans do not know their serologic status, and public health officials believe that this population is fueling the 40,000 new cases of HIV infection that occur each year. Since the late 1990s, the United States has been losing ground in the fight against HIV and AIDS. The number of deaths from AIDS has plateaued rather than decreased, and the rate of new HIV infections is on the rise in some populations.

window periods and false positive results. And clinics will need the ability to perform routine confirmatory testing, such as Western blot analyses, among patients with positive results. These measures, along with detailed educational materials in package inserts, must be part of the home-marketing strategy.

Another controversial issue is cost. Currently, laboratories pay \$12 to \$17 for each OraQuick kit. The company expects to raise the price if over-the-counter status is approved, but it is not sure by how much. Public health officials argue that the test must be affordable to reach high-risk populations. A pilot study, sampling 240 HIV-positive

patients, showed that most would pay no more than \$15 for a test.⁴

Despite concern about affordability and the potential for the misuse of results, there is still strong support for home HIV testing. During the recent rash of false positive results, officials emphasized that the test remains an excellent screening tool, and many experts argue that the only way to halt the spread of the AIDS epidemic in the United States is to make HIV tests as simple as home pregnancy tests. If those who spoke at the FDA panel meeting in November are heard, the 20-year wait for a do-it-yourself HIV test may soon come to an end.

Drs. Wright and Katz are residents in internal medicine at Brigham and Women's Hospital, Boston, and editorial fellows at the *Journal*.

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4. Spielberg F. Over the counter HIV testing: a technology whose time has come. Presented at the FDA Blood Products Advisory Committee Meeting, Gaithersburg, Md., November 3, 2005.

Unfinished Business — Expanding HIV Testing in Developing Countries

Kevin M. De Cock, M.D., D.T.M.H., Rebecca Bunnell, Sc.D., and Jonathan Mermin, M.D., M.P.H.

When the Group of Eight (G8) major industrial countries (France, the United States, Britain, Germany, Japan, Italy, Canada, and Russia) made a commitment in July 2005 to work toward universal access by 2010 to the prevention and treatment of human immunodeficiency virus (HIV) infection and AIDS, the move brought to light an HIV-testing emergency: knowledge of serologic status is required for the appropriate targeting of services and interventions. The World Health Organization and the Joint United Nations Program on HIV/AIDS recently published revised guidelines for HIV testing,¹ but field experience in Africa indicates that testing must be greatly expanded. It seems clear that to maximize benefit, a public health approach to HIV testing and treat-

ment — including case finding and testing of partners — should become the norm.

Meeting the targets for antiretroviral treatment that had been set for the end of 2005 would have required testing as many as 180 million persons worldwide annually,² far exceeding the current rates.³ Current guidelines recommend offering testing to persons with symptoms and signs that are potentially attributable to HIV infection or AIDS.¹ However, since advanced immunodeficiency can be clinically silent, it would be more effective to offer testing to all patients attending health care facilities in locations with a high prevalence of HIV infection. Botswana, with a prevalence of more than 35 percent among people 15 to 49 years of age, has initiated such routine

testing at clinics and hospitals nationwide. Kenya is increasing routine testing of pregnant women, hospitalized patients, and patients with tuberculosis; with an “opt-out” approach, less than 20 percent have chosen not to be tested. With routine testing of inpatients in selected hospitals in Uganda, 95 percent of inpatients agreed to be tested, and the prevalence of HIV was discovered to exceed 50 percent.

Current guidelines restrict the use of routine testing to settings in which antiretroviral therapy is available.¹ We believe that the recommendations should support routine testing wherever basic HIV care and prevention are available. Such a change would improve efforts at prevention, allow infected persons to receive care such as cotrimoxazole prophylaxis, and