HOME COLLECTION KITS FOR HIV TESTING

While confidential testing for HIV infection status is widely available, anonymous testing is only available in the public sector. Concerns about discrimination, social isolation, and loss of medical insurance have prevented many high-risk persons from seeking testing in any setting. Because of either real or perceived threats to confidentiality, many high-risk people may be more receptive to testing options that do not involve their health care providers or government agencies. For example, a 1992 survey by the CDC found that while only 20% of high-risk persons had agreed to be tested for HIV, almost twice as many said they would use a home test kit if one were available. Well, now they are.

In May 1996, the FDA approved the marketing of home blood collection kits for HIV testing. Two kits, Home Access® (Home Access) and Confide® (Direct Access Diagnostics), are now available for over-the-counter purchase in Oregon. Both kits run about $40 and can be purchased at most pharmacies. In licensing these tests, the FDA concluded that the risks of home collection kits (e.g., suicides because of inadequate counseling) would be outweighed by the benefits of increasing the numbers of people who know their HIV status.

Here’s how they work: The person using the kit begins (hopefully*) by reading the enclosed instruction and counseling booklet. He or she then pricks a finger with a lancet provided in the kit, and expresses a drop of blood onto a card that is pre-coded with an identification number. The dried blood spot is mailed to the laboratory in a protective envelope, where it is tested for HIV-1 antibodies. No names are provided to the company. Clients call a toll-free number a week later, and after giving their identification number, are provided their results. If the results are positive or indeterminate, a certified counselor delivers the news in either English or Spanish. Persons with negative results get a recorded message that counsels them about the “window” period for HIV infection.

The laboratory uses an FDA-approved EIA test kit, and reactive samples are retested twice. If a sample is reactive on at least 2 out of 3 tests, the results are confirmed using a more specific test such as a Western blot. Since identical testing methods are used, the sensitivity and specificity of the tests should be the same as those performed in any other licensed laboratory.

EFFECTS ON HIV SURVEILLANCE

Unfortunately, the manufacturers of these new kits have been unwilling to share information about how many kits they sell in Oregon. They survey a random sample of those who remain on the telephone after getting their test results, and summary reports are given to CDC. However, no state-specific epidemiologic data are collected or reported. In addition, since the laboratories that process the specimens are not licensed in Oregon, they are not bound by state reporting laws. Consequently, none of the test results are reported to the Health Division. If we are to accurately keep track of the number of persons newly diagnosed with HIV infection in Oregon, it is essential that providers confirm the results of home collection kits using a conventional antibody test, and that laboratories report the results. Of course, months or years may pass before persons who test positive at home seek medical care. Thus, if home collection kits become popular among high-risk persons in Oregon, we may see an artificial decline in the number of reported new HIV infections in the coming year.

*Of course, according to Lord Acton, “Power tends to corrupt and absolute power corrupts absolutely.”

How many of the persons who become HIV infected are gay men? Injection drug users? Women who are partners of men at risk? Answering these questions is clearly important for tracking trends in the epidemic and for targeting prevention programs. Currently, risk factor information concerning persons tested for HIV is only available from counseling interviews done at public sector HIV counseling and testing sites. Because of the time and money required to get detailed risk histories, the Health Division has not required private sector providers to report such information. The proportion of HIV tests being done in the private sector has grown in the past several years; in 1995, only one-third of new HIV diagnoses were from public sector clinics. As its share of the pie dwindles, the representativeness of public sector epidemiologic data decreases. By drawing away more and more high-risk persons, home test kits may further skew the data gathered from public sector counseling interviews.

EFFECTS ON TRANSMISSION

How will the availability of home test kits affect HIV transmission? According to Donna Shalala, Secretary of HHS: “Knowledge is power and power leads to prevention. The availability of home tests should empower more people to learn their HIV status and protect themselves and their loved ones.” What is difficult to assess is the relative effectiveness of post-test counseling by phone compared to face-to-face interviews and immediate access to clinical services provided by testing through a health care provider. Linking HIV testing to effective counseling has been the centerpiece of HIV prevention efforts. Can a voice-mail message or a telephone interview work as well? This remains to be seen.

In Oregon, persons who test positive at most public sector clinics are immediately referred to the Seropositive Wellness
Program, a comprehensive counseling and support program designed to help initiate and sustain behaviors that reduce the risk of transmission. Patients newly diagnosed in the private sector can also be referred to this program in Oregon’s most populous counties. Although many persons using home collection kits may already have adequate social support systems that will help them to sustain safer behaviors, others may not. Thus, home kits may be “empowering” to many, but others may be left in the lurch.

Partner notification and treatment, a central tenet of STD control programs, has not been a primary focus of HIV prevention in Oregon. Instead, resources have been directed to programs designed to educate people about HIV transmission and to reduce high-risk behaviors. Nevertheless, STD case investigators often do assist HIV-positive persons with notification of their sexual contacts and needle-sharing partners. In 1995, 102 HIV-positive index cases were interviewed and 119 contacts were notified and counseled. To the extent that persons who test positive avoid contact with the public health system, our ability to conduct partner notification activities will be compromised.

COST

The need for counseling and testing services in public sector clinics will continue. At $40 a pop, many people at risk for HIV will not be able to afford home collection kits. Testing and client-centered counseling is available at a much lower cost at most public testing sites throughout Oregon, and no one is turned away because of an inability to pay. For a list of public HIV testing sites where your patients can be referred, please contact the HIV program (503/731-4029).

CONCLUSION

The availability of home collection kits will likely encourage many people to test themselves for HIV infection, especially those with higher incomes. However, as high-risk persons are “empowered” to bypass traditional medical care and disease reporting channels, our ability to prevent transmission and gauge the continuing spread of HIV may be compromised. New and creative approaches to HIV surveillance will be necessary.

Gonorrhea Up Among Gay Men

After steadily declining over the past 20 years in Oregon, the reported incidence of gonorrhea increased slightly last year (from 854 cases in 1995 to 886 in 1996). Some of that increase may reflect an increased number of cases among men who have sex with men (MSM). In general, there were dramatic declines in gonorrhea among MSM during the 1980’s. Recently, however, there has been a significant increase in the proportion of male gonorrhea cases in Multnomah County who report having sex with men—up from 51 (18%) of 279 cases in 1994 to 74 (28%) of 268 cases in 1996. An increase in gonorrhea among MSM has also been reported from Seattle and Washington, DC.

The reasons for this increase are under investigation. Health care workers should be alert to the possibility of gonococcal infection among MSM presenting with urogenital, rectal, or pharyngeal complaints, and should consider pharyngeal and rectal cultures. Confirmed cases should be reported to the local health department. Sexual contacts of persons with gonorrhea should themselves be tested, and not just treated empirically. Local health departments and their disease intervention specialists can assist with case-contact notification and management.

REFERENCE


Influenza Update

Since the beginning of January, there has been a dramatic shift in the distribution of influenza serotypes circulating in Oregon (and nationally). By the end of 1996, 53 (98%) of 54 Oregon isolates were type A/H3N2. In contrast, only 11 (38%) of the 29 isolates obtained since then have been type A. In Washington state, where influenza seems to have hit particularly hard this year, 76 (19%) of a whopping 402 isolates have been type B—again with a marked shift since the beginning of 1997. Overall, the season seems to be petering out, with an apparent peak of activity in late December.

Due to the near absence of H1N1 isolates and the presence of two distinct H3N2 strains in circulation nationally, experts are in a quandary about the makeup of next season’s vaccine. (Although we aren’t even out of this year’s flu season, the logistics involved in vaccine development and distribution demand that these decisions be made very soon.)