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Policy Briefs
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The Use of HIV Over-the Counter (OTC) test in California from April to September 2013

Question:

Has the use of an Over the Counter (consumer-controlled) HIV test had an impact so far on the discovery of new Positives and linking them to care in California?

Background

Approval in mid-2012 of a consumer-controlled OTC HIV test by the Food and Drug Administration (FDA), which is responsible for drug and medical device approval for sales to the public, has made real the possibility of learning one's HIV status in the privacy of one's home. Now, people who are concerned about the potential embarrassment or stigma associated with receiving an HIV test from their medical provider or in a publicly-funded HIV testing site can bypass these issues to obtain a 20-minute test result if they were willing to spend the $40-$50 to purchase an OTC HIV test at a retail pharmacy. This is the latest step in the evolution of HIV testing since it first became available in 1985; now, HIV screening is no longer a cumbersome process and now doesn't require the involvement of a medical provider or community-based testing center.

The first HIV rapid screening test requiring only 20 minutes from the time a specimen (blood or mouth swab) was collected until test results were available came into wide use in California in 2004. This test, generally provided by the California Office of AIDS at no cost to its HIV testing partners, was gradually adopted by most local health jurisdictions, community-based organizations, and other groups that performed routine HIV testing. The rapid HIV test met with overwhelming acceptance by consumers in both the pilot program and as it gradually became available throughout the state from 2004-2006. Rapid HIV tests replaced a more demanding process that could require up to two weeks between specimen collection and test result availability, and often people did not return for results.

Today, rapid HIV screening tests are the standard of care in most publicly funded HIV test sites in California. It is important to note that all rapid HIV tests of this type are considered "screening" tests, as opposed to "diagnostic" tests for HIV. While the HIV rapid test is highly accurate when performed by a trained HIV test counselor or other health professional, it is still considered only a "preliminary" HIV positive test result and it must be confirmed using more sophisticated blood tests.

The company that developed and manufactured the first 20-minute HIV test, OraSure Technologies Inc. of Bethlehem, PA, began the process to have the FDA approve a consumer-controlled version of its 20-minute rapid HIV screening test in mid-2005. But the

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process was cumbersome and many individuals and organizations with a history of testing for HIV questioned the advisability of a consumer-administered HIV test. Their major concern was that individuals who tested in privacy and discovered they were HIV-positive would not receive the linkage to HIV medical care that was routinely provided when new positives were screened at clinics or publicly funded HIV testing sites. Others felt that the approval of an OTC HIV test was imperative; believing that the risks of someone not immediately being linked to HIV care were outweighed by the individual's knowledge that they were HIV positive, no matter how they learned the results, since research indicates that people change their sexual and substance-use behavior to avoid onward transmission when they become aware that they are infected with HIV.

Additionally, OraSure's clinical research indicated that the OTC test, when performed by individuals with no training except what was provided in the test kit, had high specificity and sensitivity. To increase correct use of the test, the manufacturer includes a step-by-step multilingual package insert that provides extensive information on the correct way to perform the test and maintains a 24/7 hotline (using FDA-approved scripts) for users of the OTC test.

Following a series of data review hearings by the FDA's Blood Products Advisory Committee, accompanied by public hearings that enabled HIV/AIDS advocates on both sides of the HIV OTC question to voice their views, the FDA approved the OraQuick In-Home HIV Test in July of 2012. And "Public response to the FDA announcement was swift and overwhelmingly enthusiastic " (Paltiel and Walensky, 2012)[1]. The distribution of the test to wholesalers and eventually to pharmacies in California began in September of 2012. Soon after, the test was widely available throughout the state at both chain and independent outlets.

This analysis examines the distribution, usage, and results of the HIV OTC test for a six-month period (April 1, 2013 through September 30, 2013) to determine how the HIV OTC test is being used thus far in California, after an initial start-up period. This time frame was selected as most manufacturing and distribution challenges had been overcome, and the HIV OTC test was generally available to consumers throughout California.

Methods

OraSure Technologies Inc. provided national and California-specific data on distribution, sales, and test results for this six-month period. It also provided information on the entire period the test has been available, since about September 2012, as well as some data up to March 31, 2014.

The company provided access to the manager of the 24/7 hotline, answered questions about the kinds of calls received, training for hotline personnel, and other aspects of the call center.

An HIV positive person was recruited to purchase an

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OTC test kit at a Los Angeles pharmacy in October 2013. After using the test, he contacted the 24/7 hotline operated by OraSure Techologies to see what kind of information would be provided to a newly identified positive. In order to get a full understanding of the system used when a newly-identified positive calls the hotline following the use of an OTC HIV screening test, the caller did not identify himself (beyond zip code) or indicate that he had tested HIV positive previously.

The same recruit also called back later in the month, described a potential HIV exposure 36 hours previously, and identified himself as HIV-negative on the OTC test to asses the information provided to those who test HIV-negative.

Findings

During the study period (April 1 to September 30, 2013), 2,509 OraQuick In-Home HIV tests were sold in California. However, this may not reflect all sales, as regional sales data are not available from all retail outlets, especially smaller independent drug stores. Directions in the kit instruct callers (regardless of test results) to call the 24/7-support center if they have questions about administration of the test and results. Additionally, all callers can request or be offered referrals regardless of their result. Referrals can be facilitated by providing the information to the caller and/or offering to warm transfer the caller to the requested facility or healthcare provider. Those who indicate that they've tested positive and would like to receive a diagnostic test and linkage to HIV care receive three referrals to nearby providers, assuming they provide their zip code. Personnel at the 24/7 call center are not able to ask where someone is calling from, so data on the six-month period only includes those who volunteered their California zip code when discussing a referral. During the six-month period studied, no one who verbally stated that they tested HIV-positive could be tracked back to California through the referral discussion. However, 96 people identifying themselves from California did request and accept medical referrals. Those 96 callers received referrals to 123 different medical organizations for follow-up.

From October 2012 through September 2013, nine people identified themselves as being from California through the referral process and verbally stated that they had tested HIV-positive on the OTC test. During that period nationally, 212 people identified themselves as receiving a positive test result, and 677 people requested a referral, with or without identifying their test result.

Between the Fall of 2012 and the end of March 2014, the hotline received over 27,000 calls from all 50 states and the District of Columbia, but the highest call volume to the 24/7 hotline is from three states: California, Florida, and New York (seven to 11 percent of all calls per state). Other high-volume states include Texas, Georgia, and New Jersey (four to six percent of all calls per state) and Alabama, Missouri, Illinois, Indiana, Ohio, Pennsylvania, Virginia, North Carolina, South Carolina, Tennessee and Massachusetts

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(one to three percent of call volume, per state).

Nationally, despite what information callers provide when contacting its support center, OraSure believes that the prevalence rate with its HIV OTC test is one to two percent, which is consistent with the data generated in the clinical study required by FDA for OTC approval (which yielded a 1.7 percent prevalence rate).

Based on pre-launch market research, indicating that 96 percent of consumers receiving HIV-positive test results with the In Home test kit stated they would contact a healthcare professional, as well as the number of callers who have indicated that they received a positive result with the In Home Test kit, OraSure projects that the In Home version of its HIV screening test has actually identified approximately 2,120 to 4,240 positives from October 2012 through September 2013. OraSure acknowledges that this is a theoretical projection based on prior market research and actual caller behavior but the conclusion is consistent with that seen in the clinical trials of the OraQuick In-Home HIV test.

A clinical trial based on unobserved self-testing of 5,055 individuals using the OTC test showed that 99 percent successfully obtained a result (positive or negative), 88 people of previously unknown HIV status became aware of their HIV-positive status using the OTC test (yielding the 1.7 percent prevalence data point), and that eight subjects known to be HIV-positive reported their self-test as negative. The predictive value of a negative test result using the HIV OTC test is 99.8 percent, and the predictive value of an HIV-positive test result for the OTC test is 98.9 percent based on the clinical trial. This information ultimately contributed to the FDA's approval of the in-home HIV test, but the question of linkage to care lingers. OraSure does not track the use of referrals, only that they were provided. Consumers rarely call back to inform OraSure that they accessed a referral for a confirmatory HIV test. To maintain consumer confidentiality, callers are not asked the result of their test, but 15-16% volunteer the result of their test (positive or negative.) Some choose to disclose a positive test result and many who don't disclose their result still accept a referral, indicating that they may have tested HIV- positive.

Fifteen percent of callers to the support center inquire about their HIV negative test result, possibly attempting to reassure themselves that they have conducted the test properly and have actually tested HIV-negative. These callers are questioned about how they collected the sample, the amount of time they waited to look for the result (after 20 minutes but before 40 minutes have passed), and other aspects of properly administering the test to themselves. They are also informed of the 90-day "window period." The OraQuick In-Home HIV test looks for antibodies to the HIV virus, and for some individuals it can take up to 90 days (and in rare cases, even longer) for antibodies to develop.

Some callers to the support center have only recently had what they believe may be an

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exposure to HIV. They are instructed to re-test once they are outside the 90-day window period during which HIV antibodies develop.

In an OraSure press release from October of 2013, the company indicated that "it believes more than 200,000 individuals now know their HIV status." Orasure estimates that as of March 31, 2014, 400,000 individuals have used the home HIV test to learn their HIV status.

Experience of HIV-positive Caller to OTC test Hotline

The HIV-positive recruit found the test kit is easy to understand, instructions were extremely clear, potential stumbling blocks for an in-home tester were clearly explained, and diagrams showed exactly how to collect an oral specimen, and how to place the specimen in the correct manner to achieve a valid result.

Following those steps and finding the test result was positive, he called the 24/7 hotline to report his result. As part of its agreement with FDA for approval of the HIV OTC test, OraSure had to develop scripts (approved by FDA) that are strictly followed by hotline personnel. The recruit was not asked his zip code but he volunteered it so he could obtain referrals. The person who answered the phone was empathetic, expressing concern that the caller had tested positive and explaining both that it was a "preliminary" screening test result and would require a diagnostic test for confirmation of HIV status. The caller questioned her on this and she explained the difference between the OTC test, which is classified as a preliminary HIV test, and a diagnostic test that would require a blood specimen taken by a health care professional. She asked some questions about administration of the test and apparently reassured herself that the caller had performed all the steps correctly.

The call center person, despite repeated requests from the caller, was careful to not indicate that the caller was definitely HIV-positive, although she stated the accuracy prediction of 92 percent for a positive test result. She continued to emphasize the importance of a diagnostic test at a local clinic or a visit to a physician who could also diagnose and treat, if necessary. The caller asked about available drugs, treatments, etc. and the 24/7 hotline person declined to provide that kind of information, which she again reminded would best come from a trained physician. She offered three referrals, each within five miles of the recruiter's zip code (although one was the UCLA student health center, for which the recruit would not be eligible and another is now closed but has merged with a larger Social Services agency). She offered a referral to a free clinic only when asked.

She also provided accurate information on the 90-day window period. The caller volunteered that the risk incident had occurred 48 hours before, but that he had had another risky incident about four months previously. When asked, she acknowledged that the preliminary positive test result was not likely due to the recent incident as the OTC test relies on anitbody

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development, which rarely occurs that quickly.

The recruit asked her what kind of emotional support was available after getting this news and she responded "We are not professional counselors but a physician would be able to refer you to someone."

Experience of HIV-Negative Caller to Hotline

A week later the recruit called the Hotline to ask questions about an HIV-negative test result, indicating that the potential exposure had occurred about 36 hours previously. Again, the call center person demonstrated responsiveness and knowledge of the answers to questions the recruit asked. The caller went over the steps he had taken to perform the test to assure him that he had done everything correctly. The call center person discussed the window period and emphasized that the caller should re-test in 90 days to insure that the result was still negative.

Although asked twice about anything the caller could do given that the potential exposure took place a short time ago, the call center did not offer information on seeking Post-Exposure Prophylaxis (PEP, which needs to be started up to 72 hours after a potential exposure) at a local medical facility. The caller also indicated that he was very active sexually and said he had heard of a treatment for HIV-negative people at risk for HIV, but the call center did not offer information on Pre-Exposure Prophylaxis (PrEP), which is being prescribed regularly for people at high risk of HIV acquisition. This may be due to the fact that this information is not provided in the FDA-approved scripts that the OraSure Call-in Center works from.

Conclusions

•So far, sales of OraSure's OTC test have been relatively modest, both nationally and in California. An advertising campaign was initiated close to the national introduction in 2012, and another is currently being prepared for rollout that would target African-American and Latino MSM and women in a number of cities.

•The number of calls by newly discovered HIV-positive people to the 24/7 hotline has been low, given the number of tests sold. This is especially true in California – if the number of tests sold in the six-month study period was 2,509, but no Californians identified themselves as positive (although 93 accepted medical referrals), it appears that individuals are either reluctant to disclose their positive status to an unknown person at a call center, or the positives are simply not being discovered by the OTC test. OraSure estimates that the number of positives is far greater given the results of its pre-marketing clinical research, which indicated 1.7 percent prevalence among testers.

•The test itself is easy to understand and perform for most people, although the number of calls to the hotline by people testing HIV-negative indicates that many require reassurance that they are truly negative.

•The quality of the three referrals offered to the HIV-positive recruit was not ideal: one clinic had closed, and

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another would not be able to provide services to the recruit.

•The HIV-negative caller was not provided with information on PEP or PrEP, despite inquiries to the call center. This is a missed opportunity for prevention. Given the short window of opportunity for the HIV-negative caller to potentially benefit from PEP, the call center operators should not wait for callers to inquire specifically about PEP, but should inform people who are very recently exposed about PEP. OraSure could seek FDA approval to provide information on PrEP for callers who disclose frequent potential exposures to HIV.

•For many, the OTC home HIV test remains a significant expense: the average price (excluding occasional discounts) at the three primary drugstore chains (CVS, Walgreen's and Rite-Aid) is $42.58, a not inconsiderable sum for many people at high risk for HIV acquisition.

•The question of linkage to care remains an issue as well. Although OraSure's clinical trials showed that a large percentage of newly-diagnosedHIV-positive people using the OTC test self-reported that they would contact their physician, there is no practical way for the company to follow up on new positives, given its efforts to protect callers' identities and respect their privacy.

•Given this study's findings, it is likely that at least over the near term the OraSure in-home HIV test will remain but one tool for people to learn their HIV status. The development of an in-home test that provided earlier confirmation of status could make a big difference, and work is underway to provide an OTC test that would accomplish this.

1. Paltiel A D, Walenskey RP. HIV Home Testing: Good News But Not a Game-Changer. Annals of Internal Medicine; 157 (10): Page 744-746

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