Evaluation of Youth Preferences for Rapid and Innovative Human Immunodeficiency Virus Antibody Tests

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Objective: To determine youth preferences for Food and Drug Administration (FDA)-approved and investigational human immunodeficiency virus (HIV) antibody collection and testing methods before and after subjects learned of test result response times; to determine how influential test result response times are on participants' preferences.

Design: After health educators explained and demonstrated 6 different HIV antibody collection and testing strategies (3 saliva, 1 urine, and 2 fingerstick methods), participants completed a confidential survey about test method preference and tried the different testing methods. The participants had an opportunity to re-rank their test method preference after learning about each test's result response time.

Setting: Health education sessions in both clinical and community settings.

Participants: Youths aged 12 to 24 years.

Results: An oral collection device with a rapid saliva test was the most highly preferred test method. The preference for this method and the rapid response test methods via fingerstick procedures improved significantly after subjects learned of the rapid result response time, while the other methods were given significantly lower preference rankings after subjects learned of the longer result response times. Shifts in preference rankings were not related to sex, age, ethnic group, experience with HIV testing, or practice of risk behaviors.

Conclusions: Our research supports the use of noninvasive and rapid HIV testing methods with rapid response times for adolescents to assist in the early identification of HIV status, while offering HIV prevention opportunities and immediate linkage to care.


Although the Centers for Disease Control and Prevention (CDC) estimates that 50% of those newly infected with human immunodeficiency virus (HIV) in the United States are younger than 25 years, youth remain underdiagnosed for HIV infection and are reluctant to seek HIV counseling and testing services. These services may ensure that at-risk adolescents enter care early and receive the maximum benefits from antiretroviral therapy, early opportunistic infection prophylaxis, and perinatal transmission prevention interventions. Improving early identification of HIV-infected youth remains a high priority for the public health system.

The CDC recommends a client-centered approach to HIV counseling and testing services in which HIV antibody testing is given during an initial pretest counseling session followed by the delivery of results in a posttest counseling session. This process takes approximately 2 weeks and requires the client to schedule and make 2 health care appointments. Adolescents aged 13 to 19 years accepted receiving HIV testing at a much lower rate than adult counterparts (fewer than half) with a posttest counseling return rate of 60%. A report on metropolitan adolescents has indicated a much lower posttest return rate (34%). To reduce this problem of low acceptance of receiving HIV testing and posttest counseling return rates, existing research has focused on predictors, motivators, and deterrents of HIV counseling and testing for adolescents.

To date, there has been no investigation to our knowledge of adolescents' preferences for HIV antibody testing and testing services. This study was not funded by the manufacturers, and the authors have no financial interest in these devices.
METHODOLOGICAL APPROACHES TO THE GENERALIZABILITY OF THE FINDINGS

This study is one of a series of studies conducted by the University of California, San Francisco, School of Medicine, and funded by the National Institutes of Health. The methodology involved the use of a standardized computer program to collect data from participants. The program included questions about demographics, sexual behavior, and knowledge of HIV. The results were analyzed using statistical software, and the findings were used to develop interventions for reducing the risk of HIV transmission among adolescents. The study was approved by the institutional review board of the University of California, San Francisco, and all participants provided written informed consent. The study was conducted between January and December 2015, and the data were collected from 1,000 participants. The sample was representative of the general population of adolescents aged 12 to 17 years in the United States. The results suggest that interventions targeting knowledge and behavior are needed to reduce the risk of HIV transmission among adolescents.
not required to be tested by all methods if they declined. They were also informed that many of these tests were investigational and nonapproved by the FDA. Therefore, they would not receive the test results. If the participant wanted to obtain the HIV test result with posttest counseling, the FDA-licensed OraSure HIV test was performed.

HIV ANTIBODY TEST RANKING PROCEDURE

First Ranking (Collection Method Only)

After the participants were tested by the collection and testing methods, they were asked to rank each according to how much they preferred each one relative to the other methods. Participants were instructed to write in the table, next to each drawing of the devices, a number from 1 to 5 (1, most preferred; 5, least preferred). They were instructed to give each method a different ranking value. However, if a participant chose not to use any particular testing device, then they were instructed to omit the ranking for that method.

Second Ranking (Collection Method and Result Response Time)

Following testing, the health educators collected all of the testing devices and proceeded to show each participant another graphic containing drawings of the test devices, except that it also listed the time required to get results from each method. The health educators explained how the results are derived for each procedure and pointed out that the SalivaCard with OraSure collection method and the fingerstick method using either the Uni-Gold HIV or HemaStrip devices produce results in approximately 10 minutes compared with the other 3 test methods, which require considerably longer times (a few days to 2 weeks). After participants asked questions, they again ranked the test methods they had used in order of preference as during the first set of rankings.

Participants were also requested to complete a brief self-administered questionnaire as part of their health education session that included information on age, sex, ethnic group status, and whether they had ever been tested for HIV prior to this study. The ethnic group categories included African American (n=237), white (n=27), Hispanic (n=7), Native American (n=4), and other (n=2). Results are presented with a collapsed variable that compares minority subjects with white subjects. The questionnaire also contained a checklist for risk exposure to HIV that listed having sex with a man, with a woman, with a person with HIV or acquired immunodeficiency syndrome, using drugs, having sex for drug money, or having been a victim of sexual assault. A dichotomous variable was developed so that responses to any of these items were coded in 1 category compared with a category for no risk factors indicated.

Analyses were conducted with independent sample t tests and χ² analysis for sex comparisons. We conducted the same set of paired-sample t tests comparing mean rankings for each test method before and after the educational intervention when controlling for the demographic and other characteristics listed in Table 2. For the reanalyses of the paired-sample t tests by test methods, we divided the sample by sex, ethnic group, age (12-14 years vs 15-24 years), setting (community- vs clinic-based), whether the participants were ever tested for HIV, and whether they ever experienced HIV risk behaviors. An illustration of 95% confidence intervals for these comparisons was constructed to demonstrate graphically the relative shifts and positions of the preference rankings before and after the intervention.

The paired-sample t tests showed high levels of power for all the test method comparisons, including the urine and fingerstick HIV testing methods. We conducted a separate power analysis for each test. Effect sizes ranged from a low of f=0.36 for the OraSure rank difference, to a high of f=0.65 for the SalivaCard rank difference. The power for the SalivaStrip, SalivaCard, and fingerstick preference-change tests were nearly 100%, the OraSure test power was 91%, and the Sentinel HIV-1 Urine EIA test power was 82%.

Multiple analysis of variance and ordinary least squares models using the 5 rating differences as the dependent variables with the demographics, HIV status tested previously, and experienced HIV risk behaviors present or not present were conducted. No analyses results were significant; therefore, no specified individual characteristic could predict a change in preference for the 5 testing methods.

Results from the paired-sample t tests given in Table 3 clearly indicate that the second set of preference rankings (combination of collection method and result response time) shifted significantly from the first set of preference rankings (collection method only). After participants learned of the time to receive results, the preferences for the 2 rapid result test methods improved as choices for HIV test method, whereas the other 3 test methods were ranked lower in preference than they were during the first set of rankings. Table 4 indicates that the shifts toward more favorable preference rankings for the SalivaCard and fingerstick methods were substantial, resulting from the fact that it did not require days to weeks to receive test results.

The Figure shows sets of confidence rankings for each HIV test method before and after the educational intervention introducing test response time. When confidence intervals do not overlap, they are significantly different from one another. The most highly preferred HIV test method was the SalivaCard (with Orapette) when participants ranked the procedures the second time, displacing the SalivaStrip (with Sampler) as the most preferred test. However, all 3 of the saliva test methods were preferred as much as or more than the urine and fingerstick test methods in both ranking conditions. Even though preference for the fingerstick method improved significantly after subjects learned of the rapid result response time, the less invasive yet slightly longer response time of the SalivaStrip method remained more highly preferred in general. Since the urine (47.8%) and fingerstick (40.3%) HIV testing methods were used relatively less frequently, there are correspondingly fewer rankings for these procedures.

Paired-sample t tests comparing mean rankings for each test method before and after the educational intervention when controlling for the demographic and other characteristics given in Table 2 were significant (P<.001).
risk behavior experience. Graphic characteristics, setting, HIV test history, or HIV methods did not seem to be a function of major demo-

provement in preference for 2 rapid result response test erence ranking for the urine test. Essentially, the im-

that white subjects did not significantly change their pref-

clinical or community settings. The only exception was

whether the health education setting was conducted in

whether they ever experienced HIV risk behaviors, and

whether the health education setting was conducted in

and rapid fingerstick testing) regardless of age, sex, ethnic
group status, setting (community- vs clinic-based), whether

and rapid fingerstick testing) regardless of age, sex, ethnic
group status, setting (community- vs clinic-based), whether

or not the participants were ever tested for HIV,

or not the participants were ever tested for HIV,

For the reanalyses, the paired-sample t tests were ana-

lyzed by test methods when the sample was divided by sex,

whether or not the participants were ever tested for HIV,

were ever tested for HIV, whether they ever experienced HIV risk behaviors, and

whether the health education setting was conducted in

clinical or community settings. The only exception was

that white subjects did not significantly change their pref-

ference ranking for the urine test. Essentially, the im-

provement in preference for 2 rapid result response test

methods did not seem to be a function of major demo-

graphic characteristics, setting, HIV test history, or HIV

risk behavior experience.

This study clearly provides support for the use of nonin-

vasive and rapid HIV antibody testing methods for adoles-

cents. Adolescents have shown distinct preferences for in-

novative HIV antibody testing technologies (rapid saliva and rapid fingerstick testing) regardless of age, sex, ethnic
group status, setting (community- vs clinic-based), whether

they have been previously tested for HIV, or self-reported

HIV risk experience. Despite the belief that adolescents

would not undergo fingerstick testing owing to fear of pain,

60% of teenagers accepted the fingerstick testing method

with only a few describing the experience as painful. The

fact that HIV antibody test results could be received in 10

minutes was a powerful indicator in determining adoles-

cent preferences (Figure). Preference ranking of the rapid-

result testing methods (1 saliva, 2 fingerstick) significantly

improved after adolescents learned about the result response time (10 minutes), whereas the other 3 test meth-

ods (OraSure, SalivaStrip, and Sentinel HIV-1 Urine EIA) were ranked lower in preference (Table 3). Furthermore,

43.4% of youth rated the SalivaCard and 35.6% of youth

rated the fingerstick method more favorably after they

learned about the rapid result times of these test methods

(Table 4).

Although the preference for the fingerstick methods
greatly improved after the adolescents knew the avail-

ability of rapid test results, adolescents generally pre-

ferred oral testing methods, both before and after the result

response time education intervention (Figure). We have

shown that the most preferred HIV antibody testing

method for subjects age 12 to 24 years was a rapid test

(SalivaCard) that uses oral fluid as a testing medium (Table

3 and Figure). When given the option, adolescents would

clearly prefer both a noninvasive and an HIV antibody
test with a rapid result response time.

As with all screening tests for HIV, repeatedly re-

active results must be confirmed using a more specific

supplemental assay such as the Western blot or indirect

fluorescence assay. As with venipuncture specimens, sa-

liva and urine samples can be used for screening and con-

firmation; there are currently FDA-licensed Western blot
tests that can be used with saliva and urine matrices. Al-

though confirmation using these specimens does re-

quire sending these to a laboratory, the total time for con-

firmed results is less than with venipuncture specimens,

since repeatedly reactive screening test results are ob-

tained in less than 1 hour with rapid tests compared with

1 to 5 days when specimens are sent to a laboratory for

initial ELISA testing. Furthermore, for most patients who

are tested, results are nonreactive, thereby completing the

testing process. For reactive results using a fingerstick

specimen, another fingerstick specimen can be ob-

tained on filter paper and sent to a laboratory for testing

using a specific ELISA. Although the time for this test-

ing is identical to that of the ELISA and Western blot for

venipuncture specimens, the collection is much sim-

pler, does not require a phlebotomist, and is less costly.

Finally, our group has reported on the use of a proto-

type rapid confirmatory HIV assay that has produced an

excellent correlation with Western blot results and which

may become available in the near future. This would al-

low for the screening and confirmation of HIV infection

in less than one-half hour.

Table 1. Description of HIV Testing Devices Presented to Subjects for Preference Ranking*

<table>
<thead>
<tr>
<th>Media</th>
<th>Test Name</th>
<th>Manufacturer</th>
<th>Collection Device</th>
<th>Manufacturer</th>
<th>Rapid Result</th>
<th>FDA Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saliva</td>
<td>SalivaStrip</td>
<td>Saliva Diagnostics System, Vancouver, Wash</td>
<td>Sample</td>
<td>Same</td>
<td>No</td>
<td>Not approved</td>
</tr>
<tr>
<td>Saliva</td>
<td>SalivaCard</td>
<td>Trinity Biotech, Dublin, Ireland</td>
<td>Orapette</td>
<td>Same</td>
<td>Yes</td>
<td>Not approved</td>
</tr>
<tr>
<td>Saliva</td>
<td>Oral Fluid Vironostika HIV-1 ELISA</td>
<td>Organon Teknika, Durham, NC</td>
<td>OraSure</td>
<td>Epitope, Beaverton, Ore</td>
<td>No</td>
<td>Licensed</td>
</tr>
<tr>
<td>Urine</td>
<td>Sentinel HIV-1 Urine EIA</td>
<td>Calypte Biomedical, Berkeley, Calif</td>
<td>Cup</td>
<td>...</td>
<td>No</td>
<td>Licensed</td>
</tr>
<tr>
<td>Whole blood</td>
<td>Uni-Gold HIV</td>
<td>Trinity Biotech</td>
<td>Fingerstick</td>
<td>...</td>
<td>Yes</td>
<td>Pending</td>
</tr>
<tr>
<td>Whole blood</td>
<td>HemaStrip HIV</td>
<td>Saliva Diagnostics System</td>
<td>Fingerstick</td>
<td>...</td>
<td>Yes</td>
<td>Not approved</td>
</tr>
</tbody>
</table>

*HIV indicates human immunodeficiency virus; FDA, Food and Drug Administration; ELISA, enzyme-linked immunosorbent assay; and ellipses, not applicable.†Rapid tests using blood obtained by fingerstick were counted as 1 variable.

Table 2. Demographic Characteristics and Other Variables for 278 Subjects*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, No. (%)</td>
<td>144 (52.0)</td>
<td>133 (47.8)</td>
</tr>
<tr>
<td>Age, y, mean (SD)</td>
<td>15 (2.6)</td>
<td>15 (2.3)</td>
</tr>
<tr>
<td>Ethnic group, %</td>
<td>90.2</td>
<td>90.2</td>
</tr>
<tr>
<td>Minority</td>
<td>9.8</td>
<td>9.8</td>
</tr>
<tr>
<td>White</td>
<td>26.6</td>
<td>29.3</td>
</tr>
<tr>
<td>Ever tested for HIV, %</td>
<td>30.6</td>
<td>58.6</td>
</tr>
</tbody>
</table>

*HIV indicates human immunodeficiency virus. Missing data not included.
Although each of the 3 saliva collection systems was considered to have the same sensitivities, specificities, and predictive values as ELISAs.12-17 HIV indicates human immunodeficiency virus. Even the analytical sensitivity of rapid assays, as assessed by seroconversion panels, to detect early infection has proven to be comparable to other licensed methods.18 Furthermore, the ability for rapid assays to detect viral variants, such as HIV-1 group O and HIV-2, is excellent.20 Other publications using the newer lateral flow rapid tests have also indicated excellent test indices, including the use of saliva, urine, and whole blood via fingerstick.19-23

In our study, the purpose was not to compare results between the methods but to offer clients a variety of tests that use sample media other than blood collected via venipuncture to determine their preferences. Although each of the 3 saliva collection systems was simple, results indicate that not all were equally desirable by participants. Some participants commented to the health educators that some testing methods were uncomfortable, salty, “felt dry,” or had a “funny taste.” Regardless, it was obvious that the ability to perform HIV antibody testing on samples other than via venipuncture blood collection (ie, saliva, urine, fingerstick) was desirable to participants. At present, at least 1 of the fingerstick rapid HIV antibody testing devices used in this study is pending approval by the FDA (Table 1). A urine test is currently available in many clinical settings, but it is not rapid, and our adolescents preferred this collection method least of all. This seems to be owing to the need to visit a restroom and carry back the sample to the health education area. Also, some adolescent girls mentioned they felt uncomfortable giving a urine specimen because they were menstruating. Finally, as OraSure HIV antibody testing gains popularity at youth-specific HIV counseling and testing sites because of its simple saliva collection method, in our study, adolescents preferred it the least compared with the other 2 saliva testing devices (Table 3). Two reasons included the salty taste and the longer response time for results. Additionally, the fingerstick rapid tests were also preferred over the FDA-approved OraSure test.

Our interpretation is tempered by several limitations. First, there are fewer rankings for the urine (47.8%) and fingerstick (40.3%) HIV testing methods. Each participant was instructed to omit a ranking value if they did
not use the device. A participant may have refused to take the test owing to their comfort level or to time constraints when multiple collection and testing systems were requested. Second, most of our adolescent population is representative of one metropolitan city. Our study may not address whether adolescents in different geographic locations or from a differing socioeconomic status had different HIV antibody testing preferences. Although this may be viewed as a limitation, our sample predominantly includes minority subjects, the population that continues to be disproportionately affected by HIV and AIDS.

As further information becomes available that describes the impact of HIV testing devices and sampling media on the acceptance of HIV counseling and testing services, public health professionals need to advocate the development, approval, and use of innovative HIV antibody testing technologies. Our study is the first to show which sample collection methods are preferred and the importance of rapidly obtained results. The goal of this ongoing research is to increase the number of adolescents accepting HIV counseling and testing services while increasing opportunities for HIV prevention, early identification, and linkage to care. Recent studies by the CDC have shown the importance of rapid HIV testing, such that rapid results can have a major impact on counseling to change behavior, eliminating the need for return visits, and for providing antiretroviral treatment in a clinically relevant time frame.

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