Public Health Implications of Rapid Hepatitis C Screening With an Oral Swab for Community-Based Organizations Serving High-Risk Populations

Ann Drobnik, MPH, Caroline Judd, MPH, David Banach, MD, MPH, Joseph Egger, PhD, Kevin Konty, MS, and Eric Rude, MSW

The World Health Organization estimates that 170 million people—3% of the global population—are infected with HCV.1 In the United States the prevalence of anti-HCV positivity is estimated to be 4.1 million, or 1.6% of the population.2 The estimated 2.2% prevalence of anti-HCV positivity among New York City residents is higher than that of the US population.3

Approximately 75% to 85% of HCV infections become chronic increasing the risk of liver disease and progression to cirrhosis and hepatocellular carcinoma.4 HCV is a major contributor to cirrhosis-related death and is the leading indication for liver transplantation in the United States.5 Treatment with the current standard-of-care regimens of pegylated interferon and ribavirin can achieve a sustained viral response in 40% to 70% of cases, depending on genotype.6,7 However, many HCV-infected individuals are unaware of their status because of insufficient availability of HCV screening and education.8–10

The enzyme immunoassay (EIA) that tests for antibodies to HCV infection is the most commonly used HCV screening test. This EIA testing method poses several challenges in high-risk populations such as injection drug users (IDUs), the homeless, currently or formerly incarcerated people, and immigrants. Many in these groups are uninsured or underinsured and face barriers to accessing health care. EIA testing requires phlebotomy and laboratory analysis of specimens, but this limits testing in nonclinical settings such as mobile units. As finding a usable vein is one of the limitations of EIA, rapid testing may allow for increased testing capacity, and clients might benefit from more rapid access to education, counseling, and referrals.11

We performed ribonucleic acid polymerase chain reaction (PCR) testing for discordant results. We also assessed research staff perceptions through a survey and focus group.

Results. Overall, 97.5% of OraQuick and EIA results matched. Testing of discordant samples indicated that the rapid test was more likely than the EIA to provide a correct diagnosis. Research staff preferred the rapid test and identified challenges that would be overcome with its use. CBOs could benefit from increased testing capacity, and clients might benefit from more rapid access to education, counseling, and referrals.

Conclusions. OraQuick’s accuracy is comparable to the EIA. The oral swab rapid test could help HCV screening programs reach individuals unaware of their status and expand testing into nonclinical settings such as mobile units. (Am J Public Health. 2011;101:2151–2155. doi:10.2105/AJPH.2011.300251)

Objectives. Between April and September of 2009 we evaluated the accuracy of the OraQuick HCV rapid antibody test and assessed its feasibility for use by community-based organizations (CBOs) serving populations at high risk for HCV in New York City.

Methods. We compared the results of screening by OraQuick (oral swab) and enzyme immunoassay (EIA; blood draw). We performed ribonucleic acid polymerase chain reaction testing for discordant results. We also assessed research staff perceptions through a survey and focus group.

Methods

The New York City Department of Health and Mental Hygiene Office of Viral Hepatitis Coordination provides free HCV antibody testing through collaboration with community-based organizations (CBOs). We recruited participants between April and September 2009 at 6 partner CBOs that offered testing funded by the city. Five of the 6 programs provided syringe exchange services to IDUs through storefront drop-in centers, mobile units, and multiservice centers, and 2 served immigrant populations from HCV-endemic countries primarily in Africa.15 The CBOs provided a range of services, such as rapid HIV testing, case management, health education, and outreach. All had Clinical Laboratory Improvement Amendments waivers to provide rapid HIV
Hepatitis C Virus Testing

The OraQuick HCV assay uses an indirect immunoassay method to detect HCV antibodies in oral fluid or blood. The performance of the OraQuick test is described elsewhere; sensitivity and specificity for oral fluid are both greater than 98%. Briefly, an oral swab is obtained by swabbing a testing device along the full top and bottom gums; then the device is placed in a solution to process. A control line appears if the test has run properly, and a result line will become visible if the result is positive. The time between specimen collection and test interpretation is 20 to 40 minutes.

We sent all blood specimens to the New York City Department of Health and Mental Hygiene Public Health Laboratory for anti-HCV serum testing by Abbott HCV EIA 2.0 (Abbott Laboratories, Chicago, IL). If the signal-to-cutoff ratio from the EIA was between 1 and 3.8, the laboratory performed a recombinant immunoblot assay to confirm the result (Chiron RIBA HCV 3.0 Strip Immunoblot Assay; Chiron Corporation Inc, Emeryville, CA). If the amount of blood drawn was inadequate to conduct the test or the quality of the sample was compromised, we classified the test result as indeterminate. We defined an anti-HCV–positive test result as an EIA with signal-to-cutoff ratio greater than 3.8 or a positive result from the recombinant assay. Specimens from participants with discordant OraQuick and EIA results underwent qualitative HCV ribonucleic acid testing with the PCR-Cobas Amplicor HCV Test (Roche Molecular Systems Inc, Pleasanton, CA) to detect viremia. This assay’s lower limit of virus detection is 50 international units per milliliter of HCV.

Data Collection

During pretest counseling, research staff collected data on client demographics and risk factors. After providing informed consent, participants were instructed on how to self-administer the oral swab for the OraQuick rapid test. The test was set to process either in another room or in a place within the testing room where the participant could not see it. We recorded results at 20 and 40 minutes. Because the OraQuick device was not approved by the Food and Drug Administration at the time of testing, we did not tell participants the results.

Research staff performed phlebotomy for EIA testing, and participants received an appointment to return for the results. Strategies for encouraging participants to return to receive results varied between agencies and included phone calls, letters, and locating participants through street outreach. Some CBOs also offered various incentives for participation; some of these offered an incentive only for the return visit to receive results, and others offered an incentive, such as a subway fare card or a gift card for a local store, at both visits. Participants who tested positive for HCV antibody received counseling at the return visit and referral for PCR testing to determine current HCV infection status.

Following the performance of each set of tests, research staff completed a 10-question survey. They were asked to rate, on a 5-point Likert scale, the ease of test explanation, administration, and counseling for both types of tests and the perceived appropriateness of each test type for the individual tested.

We held a focus group discussion 3 weeks after specimen collection concluded. At least 1 research staff member from each study site participated. An Office of Viral Hepatitis Coordination employee with no previous involvement in the study conducted the focus group, guiding the discussion with 8 open-ended questions. These questions addressed current resources and components of the agencies’ HCV testing programs, potential changes to the programs with the introduction of rapid testing, the potential impact of the rapid test on clients, types of clients for whom oral swab rapid testing and blood-based testing would be most appropriate, and barriers that might be added or eliminated by the introduction of rapid testing at the client, staff, or agency level.

The discussion was audiotaped, and 2 staff members from the Office of Viral Hepatitis Coordination independently coded and analyzed the transcript and came to agreement on the most salient themes. They used grounded theory in coding; thus, the questions did not directly drive the themes, which emerged from responses to several of the questions during the discussion.

RESULTS

We recruited 503 participants from the 6 CBOs. The average age of the study participants was 41 years. The majority of participants were male (65.7%), and 7 (1.4%) self-identified as transgender. The study population was primarily Black (53.0%) and Latino (35.0%); the remaining participants were White (9.9%), Asian Pacific Islander (0.8%), and other races (1.3%).

The most common HCV risk factors among participants were a history of incarceration (56.6%), injection drug use (32.0%), and nonprofessional tattoos or piercing (31.6%). Some participants fell into high-risk sexual categories, such as HIV-positive status (8.1%), history of sexually transmitted infection (27.5%), and having a sexual partner who had injected drugs (20.7%) or had hepatitis C (13.1%). Fewer participants reported high-risk medical histories such as having liver disease (4.5%), receiving a blood transfusion before 1992 (2.2%), and ever having been on hemodialysis (0.2%).

Enzyme Immunoassay and OraQuick Comparison

All rapid tests yielded the same result at 20 and 40 minutes. Specimens from 486 (96.6%) of the 503 participants provided valid results.
from both OraQuick and EIA testing. Missing blood test results from 17 participants resulted from an inability to obtain a specimen after 2 attempts to draw blood, lipemia, inadequate specimen volume, or mislabeled test tube. The OraQuick and EIA tests yielded the same result for 474 (97.5%) participants (Table 1).

Results for 12 study participants (2.5% of all participants) were discordant. PCR testing was not performed on 2 specimens because of inadequate volume. Of the remaining 10 participants, 7 had valid OraQuick, EIA, and PCR test results (Table 2). In 6 of these, the OraQuick result agreed with the PCR result. Four of the nonreactive rapid tests were PCR negative and 1 was PCR positive. Two were OraQuick positive, EIA negative, and PCR positive.

Approximately half (52.4%) of the participants returned for their EIA test results. The rate of return varied from 17.7% to 83.5% across the 6 sites. The average time to return for results was 22 days (range=3–113 days).

**Experiences of Research Staff**

We surveyed CBO research staff about the 2 test types immediately after each test was completed (Table 3) and compared the responses by using a paired t test, with adjustment for test site by least square means. Respondents preferred the rapid test for use in 98.5% of client visits over the course of the study. Staff were more likely to recommend the rapid oral test than to recommend the blood-based test in 68% of client visits. Respondents preferred the rapid test for ease of explaining test procedures, administer- ing of the test, and integrating prevention messages.

Eight research staff representing the 6 CBOs attended the focus group held at the conclusion of specimen testing. Analysis of the data revealed themes and collective experiences in 7 categories: challenges of phlebotomy, challenges with patient tracking, increased testing volume, immediate results, reduced risk of needlestick injury, rapid HCV testing in combination with rapid HIV testing, and situations requiring phlebotomy.

**Challenges of phlebotomy.** Research staff described challenges in providing HCV testing through phlebotomy. One common issue was the skill that phlebotomy requires in settings with limited resources. Many agencies had high staff turnover and sometimes relied on relatively inexperienced phlebotomists, without more experienced phlebotomists available as backup when they were unsuccessful in drawing blood.

Research staff perceived that phlebotomy presented challenges for the client, particularly IDUs: “Their main concern is you’re not going to get a vein... It’s so hard to get a vein that they don’t even want to try and it’s a really frustrating experience for them.” In addition, staff cited patient beliefs about giving blood that discourage HCV testing through phlebotomy, such as fears that blood would be used for additional testing or objections among certain immigrant groups to providing blood.

**Patient tracking.** Research staff discussed the resources that go into getting clients to return for their results. CBOs make repeated phone calls, send letters, and circulate in outreach vans to locate clients. They described focusing their efforts on those who test positive and explained that following up clients whose results were negative was not a priority. Thus, crucial opportunities to provide risk reduction counseling to help clients stay HCV negative were missed. Although many CBOs offered incentives to increase acceptance of HCV testing and encourage clients to return for their results, staff said that they preferred to emphasize the benefit of knowing one’s HCV status, but acknowledged that clients, in the words of 1 staff member, “are concerned about having to come back, that’s not realistic for them.”

**Increased testing volume.** Research staff spoke about potential increased volume of HCV testing that might follow adoption of the rapid test and how that might change agency practice. They agreed that with rapid testing, more

---

### TABLE 1—Comparison of Rapid Oral Swab Test and Enzyme Immunoassay for HCV Antibody Screening: New York City, 2009

<table>
<thead>
<tr>
<th>Participant</th>
<th>OraQuick Rapid Test</th>
<th>Enzyme Immunoassay</th>
<th>PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative</td>
<td>Positive</td>
<td>Not detected</td>
</tr>
<tr>
<td>2</td>
<td>Negative</td>
<td>Positive</td>
<td>Not detected</td>
</tr>
<tr>
<td>3</td>
<td>Negative</td>
<td>Positive</td>
<td>Not detected</td>
</tr>
<tr>
<td>4</td>
<td>Negative</td>
<td>Positive</td>
<td>Not detected</td>
</tr>
<tr>
<td>5</td>
<td>Negative</td>
<td>Positive</td>
<td>Detected</td>
</tr>
<tr>
<td>6</td>
<td>Positive</td>
<td>Negative</td>
<td>Detected</td>
</tr>
<tr>
<td>7</td>
<td>Positive</td>
<td>Negative</td>
<td>Detected</td>
</tr>
<tr>
<td>8</td>
<td>Invalid</td>
<td>Positive</td>
<td>Not detected</td>
</tr>
<tr>
<td>9</td>
<td>Invalid</td>
<td>Negative</td>
<td>Not detected</td>
</tr>
<tr>
<td>10</td>
<td>Negative</td>
<td>Indeterminate</td>
<td>Not detected</td>
</tr>
</tbody>
</table>

**Note.** PCR = polymerase chain reaction.
clients would agree to be tested because they would perceive the oral fluid test to be less risky than would a blood draw. Another theme was the potential increase in reach and volume by allowing testing to take place in nonclinical settings: “We could reach people in the mobile van, which is where we do a lot of the HIV testing.”

Rapid results. Research staff discerned benefits from the rapid result that the OraQuick test provides. Clients who did not return for their results were unable to get referrals for follow-up PCR testing, medical care, and other services. Receiving the results during the initial visit would help to overcome this: “The rapid test would give us the opportunity to establish the referral and get the person set up with an appointment right then and there.” Respondents also discussed how the 20-minute processing time allowed additional time for education and counseling, which they perceived to be as important as the test itself.

Reduced risk for staff. The risk of exposure to blood-borne pathogens emerged as a concern for research staff. Oral swab rapid testing would eliminate this risk. As 1 person noted, “The thing that comes to mind if we were to replace the blood draw with the oral swab is the removal of the risk of needlestick for the phlebotomist.”

Rapid HCV testing in combination with rapid HIV testing. Much discussion focused on the precedent set by rapid HIV testing and the implications of a similar protocol for the rapid HCV test. One respondent expressed a view held by several colleagues: “Because of the already existing rapid [HIV] test protocol, it would be easy and streamlined to test for hepatitis C.” Others thought it might be more time consuming because rapid testing “means running temperatures and controls and keeping logs.” Another participant said the new test “might be more work but not a huge amount where it would make us not want to have the rapid test.” Another respondent noted that although free HIV confirmatory testing was widely available,

One of the big gaps in our hepatitis C services has been having to refer the client out to get further testing to see if they are currently infected, if they actually have hep C, or if they just have the antibodies because they cleared it.

Also discussed was offering the rapid HIV and HCV tests concurrently. Some research staff said this would be beneficial because clients could learn their status on both in 1 visit. Others expressed more concern. One asked, “What about a preliminary positive HIV and a reactive HCV? Would that be too much for someone to handle?”

Situations requiring blood-based testing. Research staff discussed specific scenarios in which blood testing might be more appropriate for a client. Among some immigrant populations, hepatitis B, whose identification requires phlebotomy, is more common than is HCV. Agencies that serve these populations therefore have to draw blood from these clients to test for hepatitis B. Others cited beliefs among some clients that the blood test is more accurate.

DISCUSSION

To our knowledge, ours was the first field trial of the OraQuick oral fluid HCV test among a high-risk urban population. The results establish that it is a well-accepted and appropriate technology for CBOs that serve populations at high risk for HCV. The level of agreement between the rapid test and the EIA demonstrated that results were highly comparable in our study population with high HCV prevalence. Results of OraQuick matched PCR results in 6 of the 7 instances in which the rapid test and the EIA were discordant.

Research staff indicated that they preferred the rapid test to the blood draw and found it to be easy to use and effective for their client population. Rapid testing offers the opportunity for people who may not otherwise be tested to learn their HCV status without encountering the challenges associated with phlebotomy and returning to the test site to receive results. Both of these are known barriers to testing high-risk populations. In our study, nearly half of participants never returned for their EIA test results. Test results that never reach patients represent scarce public health dollars wasted, and at-risk and infected individuals remain unaware of a health issue that may greatly affect their lives. Rapid HCV testing can shift valuable resources into client education, counseling, and linkage to care.

The use of rapid HCV tests in CBOs will allow for improvements in practice. Staff without phlebotomy certification can provide HCV testing potentially increasing the volume of tests or making testing available in nonclinical settings such as mobile units. Testing oral fluid rather than testing blood also eliminates the risk of staff exposure to blood-borne pathogens. Concerns about OraQuick expressed by our research staff respondents were outweighed by the perceived benefits.

Although the OraQuick test may allow more people to learn their HCV antibody status, it will not change the need for anti-HCV-positive individuals to receive PCR testing and medical care. HCV has little public funding for medical care, supportive case management, and medications. These are greatly needed for a population that experiences greater comorbidity of mental health and substance use disorders than does the general population, along with increased difficulty in accessing quality health care. A positive antibody test result has little meaning for those without access to PCR testing and medical services. CBOs can fill some of this gap by facilitating entry into substance abuse treatment and providing assistance in obtaining health care.

---

**TABLE 3—Research Staff Survey Results About Rapid Oral Swab Test and Enzyme Immunoassay for HCV Antibody Screening: New York City, 2009**

<table>
<thead>
<tr>
<th></th>
<th>OraQuick Rapid Test</th>
<th>Enzyme Immunoassay</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explaining test procedures</td>
<td>4.48</td>
<td>4.38</td>
<td>.009</td>
</tr>
<tr>
<td>Administering the test</td>
<td>4.61</td>
<td>4.03</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Integrating prevention messages</td>
<td>4.55</td>
<td>4.43</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Likelihood of recommending test again for the same client</td>
<td>4.67</td>
<td>4.17</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Appropriateness of test for particular clients</td>
<td>4.38</td>
<td>4.05</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Note. Scored on a 5-point scale with a higher score indicating a more positive experience.
insurance or access to medical providers who will see uninsured patients. CBOs are also well-positioned to offer support groups and educate clients about liver care. Even those who do not receive antiviral therapy can be offered recommended preventive measures such as hepatitis A, hepatitis B, and seasonal influenza vaccinations, as well as counseling on prevention of further liver damage through the avoidance of alcohol, drugs, and potentially hepatotoxic medications. CBOs can be an important entry point for HCV-infected individuals into the health care system to access these important, relatively low-cost preventive medical services.

Limitations

We relied on the perceptions of the CBO staff to draw conclusions about how the OraQuick test would affect clients, rather than surveying the clients directly. In addition, New York City has a large number of IDUs, and the experiences of the participating CBOs may not be easily generalized to agencies in less populated areas with smaller high-risk populations or to other types of agencies, such as hospitals or clinics.

We were not able to precisely determine the sensitivity of the rapid test. We also did not examine the effects of switching test methods on operating costs for HCV screening programs, nor did we compare the costs of the 2 types of tests.

Conclusions

Our results provide justification for use of the OraQuick rapid test in CBO settings. This first field trial of the rapid test highlighted the impact that this new technology may have on HCV screening programs. It could bring positive changes to agencies with limited resources serving populations with complex needs. Rapid testing may identify increasing numbers of HCV antibody–positive individuals, drawing attention to the disease by making more people aware of their status.

However, greater demands could be placed on the health care system as more chronically HCV-infected people enter into care. With the potential for expanded testing, it will be critical to ensure the availability of PCR testing to determine whether persons with HCV antibodies have current HCV infection and to provide sufficient medical care and other support systems for HCV-infected individuals, who often lack access to the health care system.

About the Authors

At the time of the study, Ann Drobnik, Caroline Judd, and Eric Rude were with the Office of Viral Hepatitis Coordination, and Joseph Egger and Kevin Konty were with the Bureau of Epidemiology Services, New York City Department of Health and Mental Hygiene, New York, NY. David Banach is with the Department of Medicine, Division of Infectious Diseases, Mount Sinai School of Medicine, New York.

Correspondence should be sent to Ann Drobnik, MPH, Office of Viral Hepatitis Coordination, Division of Disease Control, New York City Department of Health and Mental Hygiene, Gotham Center, 42-09 28th St, 5th floor, CN #22, Long Island City, NY 11101-4132 (e-mail: adrobnik@health.nyc.gov). Reprints can be ordered at http://www.aph.org by clicking the “Reprints/Eprints” link. This article was accepted April 5, 2011.

Contributors

A Drobnik wrote the article, assisted with the study design, and contributed to data analysis. C Judd designed and ran the study, contributed to the data analysis, and obtained the funding. D Banach contributed to the literature review and writing of the article. J Egger and K Konty reviewed drafts of the article and contributed to data analysis. E Rude supervised the study, obtained the funding, and reviewed drafts of the article. All authors helped interpret the findings.

Acknowledgments

Funding for this study was provided by OraSure Technologies, Inc.

We thank the test site research staff who recruited participants, conducted the HCV testing, and participated in the focus group.

Human Participant Protection

This study was approved by the New York City Department of Health and Mental Hygiene institutional review board. Written informed consent was provided by study participants who were tested for HCV and by research staff who participated in the focus group.

References