Rapid Point-of-Care HIV Testing in Community-Based Anonymous Testing Program: A Valuable Alternative to Conventional Testing


ABSTRACT

Our goal was to determine whether introducing rapid point-of-care (POC) whole-blood HIV testing as alternative to standard laboratory-based testing is acceptable and changes the rate of receiving test results at an anonymous testing program. From December 2001 through April 2002 all patients requesting HIV testing at Hassle Free Clinic in Toronto were offered rapid POC or standard testing. Routine clinical data was collected. All patients were invited to complete a questionnaire evaluating testing procedure. Test counselors also completed evaluation questionnaires. HIV-positive patients were invited to an in-depth interview. There were 1610 patients, 91% chose the rapid POC test. Overall 98.9% of patients received final results, compared with 93% in the previous year. Among the rapid testers, 100% received an initial result, and 18 of 22 testing positive returned for confirmatory results. Among standard testers 90.8% returned for results \((p < 0.001\) compared to rapid testers) including all of the 4 with positive tests. There were 1257 (79%) patients who completed questionnaires, 4 with positive tests agreed to interviews, and test counselors evaluated every visit. Standard testers indicated significantly greater difficulty than rapid testers with the testing procedure. Test counselors also indicated that standard testers had greater difficulty. HIV-positive patients coped well with the testing procedure and indicated high quality counseling was important. Rapid HIV testing was acceptable to patients and test counselors, provided more patients with test results and reduced total time and number of visits. High-quality pretest and posttest counseling is particularly important for rapid testers with positive results. The impact of false-positive results requires further study.

INTRODUCTION

RAPID POINT-OF-CARE (POC) testing for HIV types 1 and 2 is an increasingly important technology worldwide the potential utility of which in Canada is not yet clear. The first commercially available device was licensed for use in health care settings in this country in 2000 and withdrawn in 2002, with the second and only currently available device being licensed in 2005. During this period HIV antibody assays using both whole blood and saliva was approved for use in the United States and elsewhere. The procedure for standard testing in
Canada as in other developed countries involves drawing a venous blood sample that is transported to a clinical laboratory for initial screening by enzyme immunoassay (EIA). These samples are often batched for efficiency, meaning that a result is only available in 1–2 weeks. If the EIA is positive, a confirmatory Western blot assay is carried out prior to any result being reported to the clinician or patient, minimizing the possibility of receiving a false-positive result. In contrast, the rapid POC test offers the screening aspect of HIV testing with a result in less than 30 minutes, which if positive, requires confirmation by venous sample and standard testing with both EIA and Western blot assays.

Rapid POC testing in the context of anonymous diagnostic testing programs has potential benefits, including an increase in the number of people seeking testing, increase in delivery of test results and posttest counseling to patients, increased satisfaction, decreased time required for service providers, and improved integration of people newly diagnosed with HIV into medical care. A number of studies have suggested that these outcomes are indeed improved in settings such as sexually transmitted disease (STD) clinics, community agencies, mobile clinics and jails.4–11 None of these studies has been carried out in Canada. There are also important concerns about rapid HIV testing.12,13 Rapid testing introduces single-session counseling, which could be less adequate for patients. It also introduces a waiting period to confirm a positive screening result, a period that could be difficult for the waiting patient. Finally, the impact of false-positive rapid test results is unknown thus far. Clearly, the potential for improvement over standard testing regimens will depend on other contextual factors such as health system organization and cost, HIV-related stigma, and characteristics of those who are testing. The relevance of rapid POC testing is evident, for example, for resource-limited settings where quality controls for laboratory-based assays may be difficult and where long waiting periods for test results may not be practical.

Our aim was to evaluate the impact of offering this technology as an option to standard testing for patients requesting an HIV test at Hassle Free Clinic (HFC) in Toronto, Canada’s busiest anonymous test site. In the year prior to this study, this clinic served 3500 patients, had a return rate for results of 93%, and an HIV prevalence of 1.4%. We introduced the only licensed and commercially available test device at the time (Fast-Check HIV-1/2 [Biochem Immunosystems Inc., Montreal, PQ] using whole blood sampling from finger prick, results within 15 minutes, with laboratory-based confirmatory testing for those with positive results) as an option to standard testing.14,15 Our primary hypothesis was that people choosing rapid testing would be more likely to receive a test result and posttest counseling than those choosing standard testing. This is arguably the most important impact a rapid test could have in an anonymous testing program. Our secondary interest was whether rapid testing would be acceptable to patients and to testing counselors. To this end, we hypothesized that more people would choose rapid than standard testing, and that satisfaction for both counselors and patients would be high. We were interested in whether people choosing rapid testing were different from those choosing standard testing in terms of demographic characteristics. Finally, we wanted to explore the unique issues that arise for positive rapid testers.

**METHODS**

This prospective cohort study was carried out between December 3, 2001 and April 25, 2002 and received ethical approval from Hamilton Health Sciences McMaster University Research Ethics Board.

**Testing device**

At the time of this study, the rapid POC test (Fast-Check HIV-1/2 whole blood) was licensed by Health Canada as a type IV device for use where appropriate HIV counseling by a health care professional was available. The performance characteristics of this device were the following: sensitivity 99.89%; specificity 99.96%; sensitivity among seroconverters 100%; reproducibility 100%.6,7
The test procedure involved collecting blood from a finger prick using a capillary sampler, and observing for a visible line indicating presence of antibodies to HIV-1 or HIV-2. The entire procedure took 15 minutes or less to complete. A negative was interpreted as indicating absence of infection, or possibility of false-negative if there was suspicion of infection in the preceding 3 months (window period). A positive result required confirmation with a venous sample and laboratory-based Western blot assay, which was completed in 3 days. All completed rapid tests were examined by at least two clinic staff to verify the result. Any test in which the color reaction was not clearly negative was interpreted as provisionally positive, and followed with confirmatory testing.

The standard test required a venous blood sample to be drawn and sent to a central laboratory for assay using a protocol of EIA and Western blot techniques. A result was available within 14 days of taking the sample, and all positive EIA screening tests were confirmed with Western blot assay before a result was reported to the test counselor.

**Study procedure and participants**

The study protocol is outlined in Figure 1. Staff experienced in counseling and testing received additional training in conducting the rapid POC test. All patients requesting HIV testing were given an information sheet about the standard and rapid tests while in the waiting room. When the patient met with the test counselor for pretest counseling, the difference between the two tests was further discussed, all were asked to decide on their preferred test, and all were invited to complete the study questionnaire that they would receive at the time of their test result. Patients who agreed to the questionnaire completed informed consent prior to their test being carried out. Routine administrative and clinical data was collected on all patients. Test specimens were taken as appropriate, without collecting any identifying information on any patient. Numeric codes were used to link clinical and administrative information, specimens, and study questionnaires.

Patients who selected rapid testing and who received a negative test result completed the evaluation questionnaire following posttest counseling. There was no follow-up planned. Patients who selected standard testing and returned for a negative test result were asked to complete an evaluation questionnaire for the entire testing experience. The test counselors completed their evaluation questionnaire at the conclusion of each patient visit in which an HIV test was taken, and did this for all testing sessions regardless of whether a patient was also completing an evaluation questionnaire. Patients who had a positive rapid or standard test did not complete an evaluation questionnaire; rather, they were invited at the time of their result to participate in an in-depth semistructured interview by a researcher approximately 1 month following their test. They were offered $20 to cover costs related to their participation.

**Measurement instruments**

Administrative and clinical data routinely collected on patients in this clinic include sociodemographic characteristics (age, gender, first language), HIV risk behaviors (gender of sexual partners, injection drug use, sex with person known HIV positive, sex with person from endemic country) and previous HIV testing patterns (testing in past year, testing ever, testing at this clinic). This information was also collected on all patients during the study. A questionnaire for evaluation of satisfaction with the testing experience for both patients and counselors was developed in several steps. The literature was reviewed and extensive discussions took place among the investigators (including two who are staff members at the clinic) and among all staff of the clinic, during which relevant domains and questions were determined. Questions ultimately chosen were those that clinic staff felt would be most useful to their work and their program. A priority was placed on the questionnaires being extremely brief for the sake of ensuring a high rate of participation. An initial draft was created and revised based on staff feedback about readability and terminology. A final draft of the patient questionnaire was then pilot tested among 20 individuals (10 staff and 10 patients) and mi-
nor revisions made based in their feedback. The questionnaire for counselors was pilot-tested among 10 staff members and minor revisions were also made to this instrument.

**Sample size and analysis**

Our primary hypothesis was that people choosing rapid testing would be more likely to receive a test result and posttest counseling than those choosing standard testing. Based on the literature and on previous experience at this clinic, we estimated that 80% of patients would choose rapid testing and 20% would choose standard testing. We used a conservative assumption that 95% of rapid testers and 90% of standard testers would receive test results. With this, samples of 1299 and 260, respec-

<table>
<thead>
<tr>
<th>Patients Consentind to Questionnaire</th>
<th>Patients Declining Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=1257)</td>
<td>(n=353)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Rapid Test (n=1182)</th>
<th>Standard Test (n=75)</th>
<th>Rapid Test (n=286)</th>
<th>Standard Test (n=67)</th>
</tr>
</thead>
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<tr>
<td>Take Test</td>
<td>Take Test</td>
<td>Take Test</td>
<td>Take Test</td>
</tr>
<tr>
<td>Further Counseling</td>
<td>Wait 2 Weeks</td>
<td>Further Counseling</td>
<td>Wait 2 Weeks</td>
</tr>
<tr>
<td>(15 minutes)</td>
<td></td>
<td>(15 minutes)</td>
<td></td>
</tr>
<tr>
<td>Immediate Test</td>
<td>Return for Test</td>
<td>Immediate Test</td>
<td>Return for Test</td>
</tr>
<tr>
<td>Result and Posttest Counseling</td>
<td>Result and Posttest Counseling</td>
<td>Result and Posttest Counseling</td>
<td>Submitted for Review</td>
</tr>
</tbody>
</table>

**FIG. 1.** Study protocol.
tively, would be required in order to demonstrate a significant difference at an $\alpha$ of 0.05. For practical reasons we planned a study duration of 1 year. We predicted that this would result in approximately 3500 patients in the program (for whom we could analyze administrative data related to receiving test results) and 2100 completed patient satisfaction questionnaires assuming participation of 60%.

Data were analyzed using Statistical Package for Social Sciences (SPSS, Inc., Chicago, IL). Comparisons of demographic characteristics and testing rates between rapid and standard testers were analyzed using Fisher's exact test. Questionnaire scores were analyzed as continuous variables and compared between rapid and standard testers as means, with $t$ tests carried out not assuming equal variances.

**Study termination**

The study was terminated after nearly five months of enrolment when the Fast-Check device was unexpectedly withdrawn from the market due to the license being withdrawn by Health Canada. Concerns about test reliability at a site in Vancouver, Canada, resulted in an investigation that confirmed that certain batches were less reliable than reported in prelicensing clinical trials. Since there was no alternative test device introduced during the anticipated study period, the study was terminated. Although patients could not be contacted directly due to anonymity, recommendations of Health Canada and Ontario Ministry of Health and Long-Term Care were followed and vigorous community advertising was carried out in order to recall rapid testers to be retested through standard testing. This circumstance was an unfortunate inconvenience for patients, and most importantly may have put a small number at risk of receiving false-negative results. The relevance and testability of our study questions did, however, remain unchanged in spite of this event because all data had been collected prior to the event and test reliability was not a focus of the research. The program, the study and the patients all functioned under the assumption of prelicensing reliability. Quantity of data was ample to carry out the required analyses.

**RESULTS**

**Patient characteristics**

From December 3, 2001 to April 25, 2002, a total of 1610 patients requested HIV testing. There were 1468 (91%) who chose the rapid POC test and 142 (8.8%) who chose standard HIV testing. Characteristics of patients who attended the clinic during the study period are summarized in Table 1. The demographic picture for the population during the study period was largely male and English-speaking repeat testers with a mean age of 32 years. Among women 85% had only male sexual partners, 4.2% had female sexual partners, and 10% had both in the past year. Among men 61% had only male sexual partners, 30% had only female sexual partners, and 8.7% had both in the past year.

Only 3.3% of patients indicated that they had

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TABLE 1. CHARACTERISTICS OF ALL PATIENTS REQUESTING HIV TESTING, COMPARING RAPID AND STANDARD TESTERS

<table>
<thead>
<tr>
<th>Age (mean, yrs)</th>
<th>Rapid testers (n = 1468, 91%)</th>
<th>Standard testers (n = 142, 8.8%)</th>
<th>Total (n = 1610)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range, yrs)</td>
<td>15–77</td>
<td>17–52</td>
<td>115–77</td>
</tr>
<tr>
<td>Female$^a$</td>
<td>394 (27%)</td>
<td>56 (39%)</td>
<td>450 (28%)</td>
</tr>
<tr>
<td>First language-English</td>
<td>1166 (80%)</td>
<td>111 (79%)</td>
<td>1277 (80%)</td>
</tr>
<tr>
<td>First test ever</td>
<td>415 (28%)</td>
<td>39 (28%)</td>
<td>454 (28%)</td>
</tr>
<tr>
<td>First test ever at HFC$^b$</td>
<td>445 (43%)</td>
<td>32 (32%)</td>
<td>477 (42%)</td>
</tr>
<tr>
<td>Aware of choice of test before arriving at clinic$^b$</td>
<td>501 (34%)</td>
<td>35 (26%)</td>
<td>536 (33%)</td>
</tr>
</tbody>
</table>

$^a$Difference between rapid and standard testers is statistically significant at $p < 0.01$.

$^b$Difference between rapid and standard testers is statistically significant at $p < 0.05$.

Proportions compared using two-tailed Fisher's exact test.
risks other than sexual contact, and only three women and five men named injection drug use as one of their risk behaviours. Among those who named sexual contact as a risk, 45% did not know anything about the risk of their partners and 2.9% knew that their partners were HIV positive.

Statistically significant differences between standard and rapid testers were: standard testers were more likely than rapid testers to be female, more likely to be a repeat patient at HFC, and less likely to have been aware of the choice of tests prior to coming to the clinic. There were no statistically significant differences in the risk behaviors named above.

Test results

Test results are summarized in Table 2. Among 1610 tests 22 (1.37%) were positive with HIV prevalence of 2.82% for standard testers and 1.23% for rapid testers (relative risk [RR] = 2.3, 95% confidence interval [CI] 0.82–6.4). Among all patients 98.9% received a final test result and posttest counseling. Among the 142 standard testers there were four who tested positive and all of these returned for test results and posttest counseling. Thirteen of the negative standard testers did not return for test results.

Among the 1468 rapid testers 100% of both negative and positive testers received at least a presumptive result and posttest counseling. There were 22 (1.50%) tests interpreted as positive. All of these patients agreed to have confirmatory standard testing. Eighteen confirmatory tests were positive and four were negative (false-positive rapid screening test). All of the false-positive rapid tests had color reactions that were difficult to read and were recorded as being equivocal. Three true positive testers did not return for their confirmatory test results, thus leaving them only with presumptive, unconfirmed information. One false-positive tester did not return for their confirmatory test result. This individual had received a second rapid test that was negative, but was instructed to have confirmatory testing.

Satisfaction among patients with a negative test

Among patients with a negative test, there were 1257 (78%) that agreed to complete an evaluation questionnaire. The group who agreed was different from the group who did not agree in several demographic characteristics. Those who did not agree were more likely to be female (36% versus 26%, \( p < 0.01 \)); more likely to have a first language that was not English (27% versus 18%, \( p < 0.001 \)); more likely to have a first HIV test (33% versus 27%, \( p < 0.05 \)); and, more likely to choose standard testing (19% versus 6%, \( p < 0.001 \)). There was no difference in HIV prevalence between the two groups.

A five-point Likert scale was used to assess the quality of testing experience in several domains. Table 3 summarizes the mean Likert score for each of the evaluation questions. Ninety-nine percent of HIV negative patients were satisfied with the overall testing experience. There were, however, 17% who indicated it was difficult to decide which test to have, and 42% who found that the testing experience...
made them feel anxious. Overall, 97% would choose the same test in the future that they had chosen on this occasion.

Where there were significant differences in ratings between standard and rapid testers, standard testers rated the experience as less satisfactory. Standard testers felt they understood the difference between testing methods less well, were less convinced they had spent enough time with a counselor, felt less trusting of the counselor, felt less freedom to ask questions and were less satisfied overall. Standard testers also reported more difficulty deciding which HIV test to have. Among rapid testers 97% indicated they would choose the rapid test again whereas 91% of standard testers would choose the same test. This difference did not reach statistical significance ($p = 0.05$).

**Satisfaction among patients with a positive test**

All of the 26 patients who received a positive HIV test result were invited to return to the clinic in 2 to 4 weeks to take part in an in-person semistructured interview with the research coordinator, rather than completing the brief satisfaction questionnaire. There were 4 patients who returned for this interview and completed informed consent. As a result of the small response rate, detailed data from these interviews are not reported here. It is noteworthy that all of the 4 respondents had positive confirmatory tests. They indicated that stress during the waiting period for confirmatory results was substantial and made manageable by having received compassionate posttest counseling, that they were happy with having chosen the rapid test, and that they would choose the same test again.

**Patient awareness of rapid testing**

We asked all patients whether they had been aware before coming to the clinic that rapid testing was available. The percentage of patients who reported being aware increased over the study period. There was 19.3% who were aware of this choice in December 2001, and 46.2% that were aware of this choice in March 2002.
Satisfaction among test Counselors

All counselors completed a questionnaire about their own satisfaction with each of the 1610 testing sessions. They were asked to rank on a five-point Likert scale the patient’s difficulty in making a decision about testing, patient’s understanding of difference in the tests, patient satisfaction with test experience, ability to support patient, adequacy of time for counseling, and overall satisfaction. Counselors reported being satisfied with the testing experience overall for 96% of testing sessions, but their mean score for ease in decision-making was significantly lower for standard than rapid testers (3.95 versus 4.34, \( p < 0.01 \)).

Test counselors were asked to indicate the duration of the entire test session for rapid testers, and of the first test session only for standard testers. The mean time required to complete the testing session was 23 minutes for both groups of testers. An additional visit and posttest counseling for the standard testers was required and was not included in this sum.

DISCUSSION

Rapid testing was the preferred option in a large anonymous testing program when offered as an alternative to standard testing. During the time rapid testing was available, a higher than usual proportion of patients received test results, and all who received no results were negative testers. Satisfaction with the testing experience was high for both patients and test counselors, and time required for the complete testing process was less for rapid test patients than for standard test patients. For these reasons, introducing rapid testing to an anonymous testing clinic appears to be beneficial.

There was an important difference between patients choosing rapid and standard testing. Standard testers appeared to have more difficulty making a decision about type of test, were more anxious about the testing process overall and were less likely to agree that they would choose the same type of test again. This was consistently indicated by the patients and by test counselors. One interpretation of this finding is that patients who were more anxious about testing or who found the choice of tests difficult tended to choose a more familiar approach rather than a more novel and possibly more risky option. It is also notable that standard testers were more likely to be repeat patients at the clinic, and possibly more attached to a certain format of standard testing.

HIV prevalence in our study population was 1.37%, consistent with the preceding year when prevalence was 1.4%. Although not reaching statistical significance, there was a trend to higher prevalence in the standard testers. This raises the question whether patients who were HIV positive had some idea of their increased risk that led them to choose a more trusted test device, or to choose the option that would delay a result and in some sense soften the impact. It is also possible that the rapid test delivered some false negative results, especially in light of the discovery of less than expected sensitivity in some product batches at other test sites that led to withdrawal of the device from the market. Under the assumption of high reliability that led to licensure of the product, however, no HIV-positive patient in the program was left without at least some information about their HIV status. There were three patients whose positive rapid tests were confirmed HIV positive but who did not receive confirmed results. We have no way of knowing whether these patients would have returned for confirmatory results if they had undergone standard testing, in which case they would have had no information about their status. We also have no way of knowing what impact a presumptive positive result has had on their well-being or on their risk behaviors, but we speculate that the impact is similar to that of receiving a confirmed positive result.

Participation in evaluation interviews for patients testing positive was small, limited to men, and limited to rapid testers who whose tests were true positives. This data is not generalizable for the population of patients testing positive, but the themes raised are nonetheless valid for generating hypotheses and important for program design. We can conclude that at least for some positive rapid testers, the rapid test continues to be perceived as the preferred choice even after the process is complete. Although for some the delivery of results feels
abrupt and the waiting time for confirmation difficult, there is also a perception that high quality post-test counseling is an important component of coping for these patients. The patients who had inconclusive or positive rapid test results and did not return for their confirmatory negative results remain a concern. Receiving inconclusive information may lead to unnecessary anxiety and may also have an impact on risk behaviors.

Nonreturn for standard HIV test results may be a more significant problem in the United States than in Canada. The U.S. Centers for Disease Control and Prevention reported in 2000 that among publicly funded testing clinics 30% of those testing HIV negative and 39% of those testing positive did not return for results. Several evaluations from the United States have shown dramatic increases in numbers being tested, increases in the proportion who receive final results, and in general acceptability to patients and staff. In a New York study, 96% of patients chose the rapid test and 100% of rapid testers received results compared with 85.8% of standard testers. A concern was that 80% of trained counselors felt “very uncomfortable” delivering positive rapid test results. Another group reported that giving rapid test results was stressful and felt too quick for some patients. Some have reported not only on the testing process but on the impact on engaging with care, finding that length of time to receive medical care is reduced and retention in care increased for those who have rapid tests.

The analyses in which we used routine administrative and clinical data included all participants in the program, making these reliable and generalizable to the population of clinic patients. Similarly, the evaluation questionnaires of counselors were completed for all patient visits. The patient evaluation questionnaires were completed by 78% of patients who tested negative. Although this suggests reliable and generalizable results, we also found significant differences between the patients who completed questionnaires and those who did not. Those not completing questionnaires were more likely women, non-English speaking, standard testers for whom this was a first test. We could speculate that these people being excluded from the evaluation analysis might bias our results in the direction of greater satisfaction. It is reassuring, however, that the HIV prevalence was the same for the two groups, thus suggesting similar risk behaviors.

In summary, our study findings indicate several important reasons to offer rapid HIV testing in anonymous testing programs. They also highlight that high quality test counseling is essential, primarily to ensure that patients understand the meaning of a rapid test result, and to facilitate a prompt coping response for people who receive a positive or equivocal test result. Our study leaves unanswered the question of how both true- and false-positive rapid tests affect patients who do not receive confirmatory results.

ACKNOWLEDGMENTS

We wish to remember our colleague Robert Trow whose vision it was to make HIV testing accessible to all; to share our appreciation for the participants and clinic staff who gave their valuable time to the study; and, to acknowledge the support of the AIDS Bureau of Ontario Ministry of Health and Long-Term Care which funded this research.

REFERENCES


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