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Relative Efficacy of Prevention Counseling With Rapid and Standard HIV Testing: A Randomized, Controlled Trial (RESPECT-2)

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Background: **Two risk-reduction counseling sessions can prevent sexually transmitted diseases (STDs); however, return rates for test results are low.**

Study: **A randomized, controlled trial compared rapid HIV testing and counseling in 1 visit with standard HIV testing and counseling in 2 visits. Main outcomes were STDs (gonorrhea, chlamydia, trichomoniasis, syphilis, HIV) within 12 months. Participants were 15- to 39-year-old STD clinic patients in Denver, Long Beach, and Newark. STD screening and questionnaires were administered every 3 months.**

Results: **Counseling was completed by 1632 of 1648 (99.0%) of the rapid-test group and 1144 of 1649 (69.4%) of the standard-test group. By 12 months, STD was acquired by 19.1% of the rapid group and 17.1% of the standard group (relative risk [RR], 1.11; confidence interval [CI], 0.96–1.29). STD incidence was higher in the rapid-test group than in the standard-test group among men (RR, 1.34; CI, 1.06–1.70), men who had sex with men (RR, 1.86; 95% CI, 0.92–3.76), and persons with no STDs at enrollment (RR, 1.21; 95% CI, 0.99–1.48). Behavior was similar in both groups.**

Conclusions: **Counseling with either test had similar effects on STD incidence. For some persons, counseling with standard testing may be more effective than counseling with rapid testing.**

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IN THE UNITED STATES, in 1998, there were 621,150 human immunodeficiency (HIV) tests done in sexually transmitted disease (STD) clinics and 7731 were positive.[1] HIV-negative persons visiting STD clinics are at a relatively high risk of becoming infected with HIV[2] and of having subsequent STDs.[3] It is thus important that STD clinics provide effective interventions to prevent HIV and other STDs. Project RESPECT showed that for STD clinic clients, 2 20-minute sessions of prevention counseling with HIV testing, given a week apart, decreased the risk of acquiring an STD during the following year 20% more than HIV testing with 2 sessions of information alone.[3] In practice, however, it is often not

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possible to deliver 2 prevention counseling sessions in STD clinic settings because many clients do not return for their HIV test result.[1,4,5] In U.S. STD clinics, the overall rate of return for HIV test results was 44.9% in 1998.[1] Contacting HIV-positive clients who do not return for their HIV test result consumes time and resources.

Rapid HIV tests make it possible to provide HIV testing, counseling, and the test result, in 1 clinic visit, overcoming the problem of clients not returning for test results.[6,7] Although other studies have shown that rapid HIV testing increases the proportion of persons who learn their HIV test result,[6,8] immediate knowledge of HIV test results could be an important modifier of subsequent behavior change. We are not aware of any studies that compare the efficacy of counseling with rapid testing to counseling with standard testing. We therefore compared the efficacy of counseling and testing with a rapid HIV test in 1 visit with counseling and testing with a standard HIV test in 2 visits.

Materials and Methods

Study Design

We conducted a multicenter, randomized, controlled trial. At enrollment, participants were randomly assigned to receive prevention counseling with either a rapid HIV test or a standard HIV test. Half the participants in each HIV test group were also randomly assigned to receive an additional (booster) counseling session 6 months later. The effects of booster counseling are reported elsewhere.[9]

Setting and Study Population

Participants were recruited from 3 public STD clinics in Denver, Long Beach, and Newark. All 3 clinics had participated in Project RESPECT.[3] Eligible clients were those who came to the clinics for a full diagnostic STD examination, were HIV-negative at enrollment, had had vaginal or anal sex in the preceding 3 months, and were aged 15 to 39 years. Participants at the Newark site were aged 18 years or older because of a local Institutional Review Board requirement for parental consent for enrolling minors, which was not feasible for our study. Participants were also required to be fluent in English (as judged by the screener), to be willing to return for follow-up visits, and to provide written informed consent. Persons enrolled in HIV vaccine trials were ineligible, and participants were not permitted to enroll more than once. During the recruitment phase, study staff nonselectively screened as many clients as possible for eligibility. Participants with a confirmed positive HIV test result at enrollment were referred for care and were ineligible to continue in the study. This exclusion was planned in advance and was specified in the study protocol and the consent form.

HIV Testing

At enrollment, all participants received their first counseling session and were tested for HIV antibodies. The Single Use Diagnostic System for HIV–1 (SUDS) test (Abbott-Murex Diagnostics, Norcross, GA) was used for rapid HIV testing. After blood collection, this test takes approximately 20 to 30 minutes. Standard testing was done using the HIV enzyme immunoassay (EIA) in use at each clinic; the Denver and Long Beach clinics used serum specimens, and the Newark clinic used oral fluid specimens (OraSure; OraSure Technologies Inc., Bethlehem, PA). All positive (repeatedly reactive) HIV test results were confirmed using Western blot, regardless of the type of HIV test used for the initial screening.

Participants in the rapid-test group were also given their HIV test result and a second counseling session during the initial visit. They were also given a clinical examination for STDs. Most participants in the rapid-test group did not have to spend additional time waiting for their HIV test result because the test was performed while they were being examined. Participants with a preliminary positive test result were asked to return to the clinic a few days later for their confirmatory test result. Persons with confirmed positive results were referred for care and excluded from the study.

Participants in the standard-test group were given a clinical examination for STDs during the initial visit and were scheduled to return 1 week later for their HIV test result and second counseling session. A reminder letter to return for their HIV test result and second counseling session was mailed the day after enrollment, and a reminder telephone call was made the day before the scheduled second visit. Those who did not return for their second counseling session as scheduled were phoned 1 or 2 more times and were sent another reminder letter. Outreach efforts were discontinued after 28 days unless the participant had a positive HIV test result. Those in the standard-test group who did not complete their second session within 28 days from the initial visit were considered not to have completed the intervention, but on request, they were given their HIV test result and counseling according to usual clinic practice at subsequent clinic visits. All participants were given $10 for completing the enrollment visit. Those assigned to the standard-test group were not compensated for returning for their HIV test result and second counseling session.

Counseling Interventions

Counseling interventions were based on the 2-session "brief" counseling intervention used in Project RESPECT.[3] This intervention complied with the approach to counseling recommended by the Centers for Disease Control and Prevention (CDC)[10] at the time of the Project RESPECT study and with the revised CDC guidelines,[11] published in 2001 while the current study (RESPECT-2) was in progress. This intervention integrates theoretical principles from several models of behavior change interventions but is not based on a single theoretical model. The counseling techniques are similar to motivational interviewing[12] and include both cognitive and action-oriented strategies.

In our study, the standard-test group received the original 2-session intervention used in Project RESPECT. The counseling protocol was modified for use with a rapid HIV test, but the modifications were kept to a minimum to make the rapid-test intervention as similar as possible to the original intervention. The intervention was designed to take approximately 40 minutes for both counseling sessions with the standard test and approximately 30 minutes with the rapid test. The main differences between the 2 interventions were in the number of visits required to complete the intervention (1 or 2 visits), the waiting time for the HIV test result, and whether the participants had an opportunity to try an initial risk-reduction plan and discuss their effort at the second counseling session.

Quality Assurance of the Interventions

Written quality assurance procedures were followed to ensure quality and consistency of the counseling interventions. These procedures required that at least 10% of counseling sessions be reviewed using a structured quality assurance tool. Trained supervisors at each site were required to observe at least 5% of sessions in person and to review audiotapes of an additional 5% of sessions. Sessions were chosen for in-person observation on a convenience basis, but the counselor supervisor at each site was expected to

observe a minimum of 2 counseling sessions per counselor per month. At enrollment, 5% of participants were randomly assigned to have all their counseling sessions audiotaped. Supervisors held regular staff meetings with counselors to discuss counseling issues and to provide additional one-on-one coaching as needed. Two monitors from the CDC observed counseling sessions during semi-annual site visits and reviewed a random sample of audiotaped counseling sessions from each site.

Outcomes

Outcomes were measured at 13-week intervals, scheduled 3, 6, 9, and 12 months from the date of enrollment. Before each follow-up visit, study staff mailed a reminder letter to each participant and made a reminder phone call. When participants did not keep appointments, staff mailed additional reminder letters and made phone calls to reschedule the visit, as needed. Participants who were due for a study follow-up visit were screened for STDs and interviewed if they visited the clinic any time from 1 week before the due date up to 12 weeks after the due date. Participants were given $25 for completing each follow-up visit. This was later increased to $50 in an attempt to improve retention rates.

The primary outcome was STD incidence over the 12 months after the intervention. STD incidence was measured using the combined results of tests for gonorrhea, chlamydia, trichomoniasis, syphilis, and HIV infection. Participants were tested for all 5 infections at the enrollment visit and were screened for gonorrhea, chlamydia, and trichomoniasis at each quarterly follow-up visit. Participants were routinely retested for HIV and syphilis at the 12-month visit and at other visits on request. STD test results and treatment details were abstracted from clinic charts for all clinic visits during the follow-up period, including visits not related to the study.

An incident STD was defined as a positive laboratory result either preceded by a negative result for the same STD or detected more than 14 days after documented treatment with antibiotics effective against that STD. STD testing was done in the local laboratories used by each clinic. Tests for gonorrhea and chlamydia were done on urine specimens by means of nucleic acid amplification tests (NAATs). The Long Beach and Newark clinics used ligase chain reaction (LCR; LCx Uriprobe; Abbott Diagnostics Division, Abbott Park, IL). The Denver clinic used polymerase chain reaction (PCR; Cobas Amplicor CT PCR and Cobas Amplicor GC PCR; Roche Diagnostic Systems, Inc., Branchburg, NJ) initially but 18 months later changed to strand displacement amplification (SDA; BDProbeTec ET CT/GC; BD Diagnostic Systems, Sparks, MD). *Trichomonas vaginalis* was cultured using the InPouch TV test (BioMed Diagnostics Inc., San Jose, CA) or modified Diamond's medium as the culture medium. Cultures were done using vaginal swab specimens from women and urine sediment specimens from men. At follow-up visits, vaginal swabs were collected by the participant (Denver and Long Beach) or a clinician (Newark), depending on local clinic policy.

Secondary outcomes were sexual risk behaviors. Behavioral data were collected using audio computer-assisted self-interview (ACASI) technology. Participants completed an ACASI questionnaire at enrollment and at each study follow-up visit. The ACASI questionnaires were developed for this study and pilot-tested in advance. The questionnaires included closed-ended questions on STD history, sexual behavior history, and other risk behavior and risk markers. The ACASI questionnaires were programmed to check responses for internal consistency, and if inconsistent responses were detected, to ask questions again. For most questions, a uniform 3-month recall period was used, irrespective of the time since the most recent study visit.

Sample Size Determination

The sample size goal was 4100 participants. We projected that 11.5% of the standard-test group would have an STD detected by the 12-month visit if 70% of participants were tested for STDs at each follow-up visit. The sample size was calculated to provide 80% power to detect a statistically significant difference ($P \leq 0.05$) if the relative risk of having an incident STD after 1 year of follow up was 1.25 or more. For sample size calculations, we assumed that there would be no important interaction between the enrollment interventions and the booster counseling intervention.

Randomization Procedures

Computer-generated randomization sequences were prepared in advance by an independent data management company. Randomization was stratified by site and gender. Within each site-gender stratum, randomization was done in blocks of variable size, ranging from 1 to 5. A separate series of sequentially numbered, sealed, opaque envelopes was prepared for each site-gender stratum. After the client signed consent to participate, the recruiter opened the next envelope in the series while the participant watched. Participants were told their HIV test assignment and whether they had been assigned to have booster counseling at the 6-month visit. Any lapses in adherence to the randomization protocol were reported to the data management company and the principal investigator at the CDC.

Allocation Concealment (Blinding)

Although participants and study staff were aware of intervention assignments, the laboratory staff who performed the STD tests were not. Preliminary analyses of STD outcomes by intervention group used coded group identifiers so that the data analysts also did not know the intervention assignment. The code was broken only after the preliminary analyses had been completed.

Data Analysis

We did an intention-to-treat analysis. Participants were grouped according to the intervention assigned by randomization, regardless of whether they received or completed the assigned intervention (intention-to-treat analysis). Relative risks were used as the primary method of comparing intervention groups. In addition, crude and adjusted odds ratios were calculated and compared to check for evidence of confounding. The odds ratios were adjusted for the baseline presence of an STD or the risk behavior being considered as well as gender and clinic site. The Breslow-Day test for homogeneity of odds ratios[13] was used to test for interaction between the testing and counseling interventions given at enrollment and the booster counseling intervention given at the 6-month visit using cumulative STD incidence from enrollment to the 12-month visit as the outcome. This test was also used to test for interaction between the testing and counseling interventions at enrollment and the characteristics considered in subgroup analyses.

Cumulative STD incidence was determined for the interval from enrollment to each quarterly study visit. Participants were classified as having either no incident STD or at least 1 incident STD by the end of the interval. The STD incidence in the 2 intervention groups was also compared using generalized estimating equations (GEE)[14] to take all incident STD episodes into account among those with more than 1 incident STD during the follow-up period. All participants were included in the analysis of STD outcomes, including those who did not return for STD screening. Many STD are symptomatic and lead patients to seek care. Thus, subjects who

return to the clinic may be more likely to have an STD than subjects who did not return. Therefore, those who were not screened were assumed not to have had an incident STD. Analyses of behavioral outcomes included only those participants with behavioral outcome data, because we did not know how various behaviors might be associated with missing visits. Behavioral outcomes were calculated for each 3-month interval and were noncumulative. We also did exploratory subgroup analyses by gender, gender of partners (among males), age group, site, and by STD infection status at enrollment. For subgroup analyses by age, participants were stratified into 3 age groups: younger than 20 years, 20 to 29 years, and 30 years or older.

The study was funded by the CDC. The protocol was approved by Institutional Review Boards at each site and at CDC.

Results

From February 1999 through December 2000, 9457 clients were assessed for eligibility. Of the 7587 found to be eligible on screening, 3342 (44.0%) consented to participate and were randomly assigned to a group (Fig. 1). Refusal rates were higher in men (60.8%) than women (48.3%), increased with age (<20 [46.3%], 20–29 [57.2%], >29 [58.6]), and varied by site, being highest at the Denver site (67.6%) and lowest at the Newark site (39.0%). We did not gather additional data from persons who refused to be in the study and therefore cannot assess their baseline risk status.

Of those enrolled, 22 participants in the rapid-test group and 23 participants in the standard-test group were later determined to be ineligible and were excluded from the study and the analyses. HIV-positive test results at enrollment caused 16 participants in the rapid-test group and 18 participants in the standard-test group to be excluded. The remaining 11 (for both groups combined) were excluded because they failed to meet other eligibility criteria; 7 reported no vaginal or anal sex in the 3 months before enrollment, 2 for coming to the clinic for reasons other than an STD examination, 1 for being over 39 years, and 1 for enrolling in the study a second time. After excluding ineligible participants, 1648 participants remained in the rapid-test group and 1649 participants remained in the standard-test group. We terminated enrollment earlier than planned because the SUDS test was unavailable for several months and no alternative licensed rapid HIV test was available. As a result, the final sample size of 3297 was approximately 20% less than our goal of 4100.

No significant interaction was evident between the initial interventions and the 6-month intervention ($P = 0.62$), so we combined the booster and no-booster groups for comparisons of the rapid-test and standard-test interventions. Baseline demographics and risk characteristics were similar in both intervention groups (Table 1). Almost 10% of men reported having engaged in sex with another man in the 3 months before enrollment. Reports of having ever participated in commercial sex or having ever injected drugs were infrequent.

Of those in the rapid-test group, 1632 of 1648 (99.0%) completed both counseling sessions and received their HIV test result (nearly always during the initial visit), compared with 1144 of 1649 (69.4%) of those in the standard-test group. Of the 16 (1.0%) in the rapid-test group who did not complete the intervention as assigned, 4 did not receive HIV testing or counseling, 10 had only the first session and did not receive their HIV result, and 2 were given the standard-test intervention in error. Of the 505 (30.6%) in the standard-test group who did not complete the intervention as assigned, 5 did not receive HIV testing or counseling, 456 had only 1 session, 43 were given a second counseling session more than 28

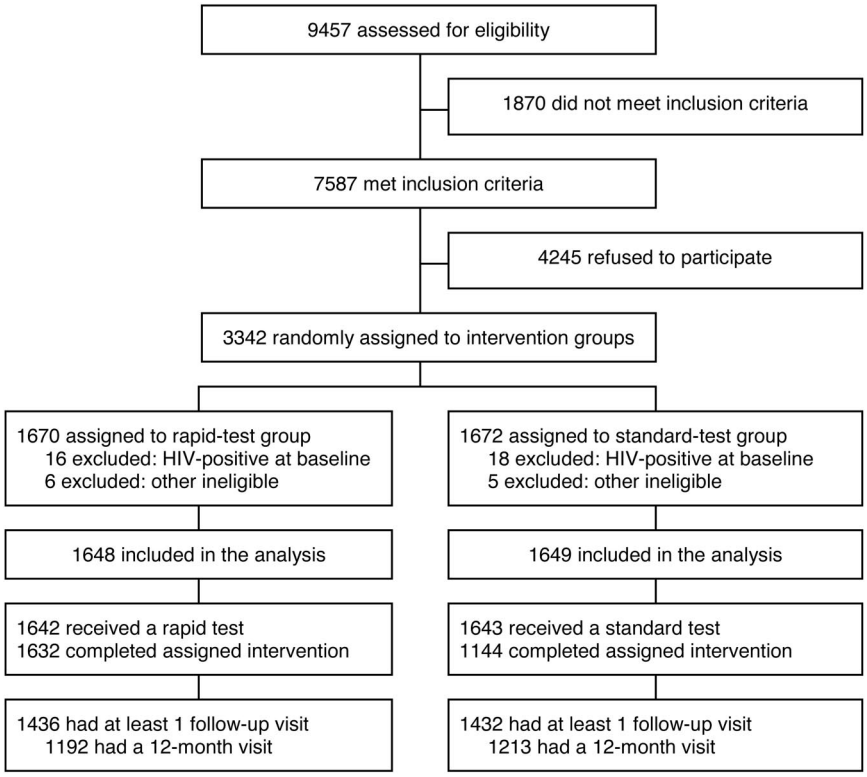

Fig. 1. Participant recruitment, group assignment, and study participation.

TABLE 1. Baseline Demographics and Risk Characteristics, by Intervention Group

Characteristic	Intervention Group	
	Rapid* (n = 1648)	Standard† (n = 1649)
Assigned to booster counseling (%)	50.0	50.3
Female (%)	45.9	45.5
Race/ethnicity (%)		
Black	49.3	51.9
Hispanic	19.0	17.3
White	22.7	21.2
Other	9.0	9.6
Age, median/mean (yrs)	24/25.4	25/25.8
Men	25/25.8	26/26.4
Women	23/24.9	24/25.0
≥High school diploma (%)	74.6	76.3
Unemployed (%)	25.9	26.4
Ever injected drugs (%)	2.3	2.2
Ever exchanged sex for money or drugs (%)	6.2	7.5
Previous HIV test (self-report) (%)	77.6	77.1
Previous STD (self-report), %	38.1	37.5
Laboratory-confirmed STD at enrollment (%)	26.5	24.4
Men	25.0	23.5
Women	28.2	25.4
Behaviors in the past 3 mo		
Male–male sex, % of men	9.8	9.5
≥2 sex partners (%)	55.7	53.8
Any unprotected sex (%)	87.3	86.2
Any unprotected sex with nonprimary partner (%)	40.5	40.0
Any unprotected sex while drunk or high (%)	39.3	38.7
Sex with new partner on day first met (%)	14.9	15.3
One-time sex partner (%)	38.7	36.6

*Rapid-test intervention.
†Standard-test intervention.
HIV = human immunodeficiency virus; STD = sexually transmitted disease.

days after the first session, and 1 was given the rapid-test intervention in error. The median time taken for the first session was 18 minutes in the rapid-test group and 25 minutes in the standard-test group. The median time taken for the second session was 14 minutes in the rapid-test group and 15 minutes in the standard-test group.

Return rates for follow-up visits were similar in both intervention groups and showed little attrition over the follow-up period (Table 2). The mean return rate for follow-up visits, averaged across all 4 follow-up visits, was 73.5% in the rapid-test group and 73.8% in the standard-test group. The proportion of participants with at least 1 follow-up visit and the proportion of participants with a 12-month visit was also similar in both groups but varied by gender (women, 77.4%; men, 69.2%) and by site (Denver, 79.9%; Long Beach, 73.1%; Newark, 64.8%). No adverse events occurred as a result of study participation.

The cumulative incidence of STDs by the 12-month visit was higher in the rapid-test group than in the standard-test group (Table 3), but this difference was not statistically significant ($P = 0.15$). Differences in cumulative STD incidence between groups were more evident at the 6-month visit and the 9-month visit than at the 12-month visit. Comparisons of incident STDs by intervention group using GEE produced similar findings (not shown).

TABLE 2. Rates of Follow-Up by Intervention Group

	Intervention Group	
	Rapid* (%) (n = 1648)	Standard† (%) (n = 1649)
≥1 follow-up visit	87.1	86.8
3-mo visit	76.4	75.0
6-mo visit	72.7	73.0
9-mo visit	72.5	73.4
12-mo visit	72.3	73.6

*Rapid-test intervention.
†Standard-test intervention.

The cumulative incidence of STDs was higher in women (23.5%) than in men (13.5%), mainly because of trichomoniasis being detected more frequently in women than in men. Among the 1507 female participants, there were 163 cases of chlamydia (10.8%), 78 cases of gonorrhea (5.2%), 169 cases of trichomoniasis (11.2%), 13 cases of syphilis (0.9%), and no cases of HIV infection. Among the 1790 male participants, there were 127 cases of chlamydia (7.1%), 114 cases of gonorrhea (6.4%), 20 cases of trichomoniasis (1.1%), 10 cases of syphilis (0.6%), and 4 cases of HIV infection (0.2%). Of the 4 cases of HIV infection, 3 were in the rapid-test group and 1 was in the standard-test group.

Subgroup analyses showed that the relative effect of the 2 interventions on STD incidence by 12 months varied significantly by gender ($P = 0.05$), but not by site ($P = 0.52$) or by age ($P = 0.58$). Among men, the relative effect of the 2 interventions was not significantly different among men who had sex with men (MSM) compared with men with no male partners ($P = 0.30$). Among men, those in the rapid-test group had a significantly higher incidence of STDs than those in the standard-test group (Table 3), both within the first 6 months ($P = 0.01$) and over 12 months ($P = 0.02$). Among MSM, the incidence of STDs in the rapid-test group was almost double that in the standard-test group at 12 months, but this difference was not statistically significant ($P = 0.08$). Among men with no male partners, those in the rapid-test group had a higher incidence of STDs than those in the standard-test group, a finding that was statistically significant for STDs acquired within the first 6 months ($P = 0.03$), but not at 12 months ($P = 0.06$). Among women, the incidence of STDs was similar in both intervention groups.

The relative effect of the 2 interventions on STD incidence differed by STD infection status at enrollment. Enrollment STD status modified the intervention effects significantly at 6 months ($P = 0.02$), but not at 12 months ($P = 0.11$). Regardless of intervention group, participants with an STD at enrollment had a greater risk of acquiring an STD during follow up than those with no STD at enrollment (Table 3). However, among those with no STD at enrollment, those in the rapid-test group had a significantly higher incidence of STDs than those in the standard-test group within the first 6 months ($P = 0.01$), but not at 12 months ($P = 0.06$). Among those with an STD at enrollment, the incidence of STDs over the next 12 months was similar in both intervention groups.

Sexual risk behaviors during the preceding 3 months were similar in both intervention groups at the 3-month visit (Table 4). Sexual risk behaviors during the preceding 3 months were also similar in both intervention groups within subgroups of women, MSM, and men with no male partners. Sexual risk behaviors in

TABLE 3. Cumulative Incidence of Sexually Transmitted Disease Since Baseline by Intervention Group and Select Participant Characteristics

	Intervention Group		
STD by Visit	Rapid* (%)	Standard† (%)	Relative Risk (95% CI)
All participants (rapid, n = 1648; standard, n = 1649)			
3 mo	6.4	5.9	1.09 (0.84–1.43)
6 mo	12.3	10.3	1.20 (0.99–1.46)
9 mo	16.1	13.6	1.18 (1.00–1.40)
12 mo	19.1	17.1	1.11 (0.96–1.29)
Gender			
Women (rapid, n = 757; standard, n = 750)			
6 mo	15.1	14.4	1.05 (0.82–1.33)
12 mo	23.3	23.7	0.98 (0.82–1.18)
Men (rapid, n = 891; standard, n = 892)			
6 mo	10.0	6.8	1.47 (1.08–2.01)
12 mo	15.5	11.6	1.34 (1.06–1.70)
MSM (rapid, n = 87; standard, n = 85)			
6 mo	12.6	8.2	1.54 (0.62–3.77)
12 mo	21.8	11.8	1.86 (0.92–3.76)
Men, no male partners (rapid, n = 800; standard, n = 809)			
6 mo	9.5	6.6	1.45 (1.04–2.03)
12 mo	14.6	11.5	1.27 (0.99–1.64)
STD status at enrollment visit			
No STD (rapid, n = 1,210; standard, n = 1,235)			
6 mo	10.0	7.0	1.44 (1.10–1.87)
12 mo	15.0	12.4	1.21 (0.99–1.48)
STD (rapid, n = 436; standard, n = 398)			
6 mo	18.8	20.9	0.90 (0.69–1.19)
12 mo	30.3	31.9	0.95 (0.78–1.16)

*Rapid-test intervention.
†Standard-test intervention.
CI = confidence interval; STD = sexually transmitted disease (baseline STDs include gonorrhea, chlamydia, trichomoniasis, and syphilis; STDs at follow up include gonorrhea, chlamydia, trichomoniasis, syphilis, and HIV); MSM = men who had sex with men.

both intervention groups were also similar at subsequent visits (data not shown).

Discussion

Overall, after 1 year of follow up, we found little difference in the incidence of STDs after rapid HIV testing with counseling compared with standard HIV testing and 2 counseling sessions; the relative risk was 1.11, a difference that was not statistically significant. Our study was designed to detect statistically significant results if the true relative risk of incident STDs in the rapid-test group compared with the standard-test group was 1.25 or larger. We thought that the other benefits of rapid testing (such as less loss-to-follow up of HIV-infected persons) would make the rapid-test intervention preferable to the standard-test intervention, even if counseling were found to be slightly less effective in the rapid-test group. Thus, the difference in STD incidence that we found at 1 year is also smaller than what we consider to be a clinically important difference.

Our results suggest that in the short term and in some subgroups, the rapid-test intervention may be somewhat less effective at preventing STDs than the standard-test intervention. Subgroup analyses, although planned in advance, were exploratory because we did not have hypotheses about differential effects. Conclusions drawn from the results of subgroup analyses are thus tentative[15] and need to be addressed by additional studies. The results suggest that the rapid-test intervention may be somewhat less effective at preventing STDs than the standard-test intervention in men but not in women. Among MSM, the STD incidence at 12 months was almost twice as high in the rapid-test group as that in the standard-test group, but there were relatively few MSM in the study and this difference is not statistically significant. Some other randomized, controlled trials have also found differences in the effectiveness of behavioral interventions by gender with more marked intervention effects in men than in women.[16–20] Interventions that promote safer sexual practices may have greater effect in men than in women because men tend to have greater control over protective measures such as the use of condoms.[19,21]

It has been suggested that receiving a negative HIV test result may disinhibit risk behavior.[22] The potential for disinhibition may be less after the standard-test intervention than after the rapid-test intervention. Clients given a standard test have counseling on 2 separate occasions, spend slightly more time with a counselor, and have 1 to 2 weeks to reflect on their risk before learning their HIV test result. Our finding of an excess risk of STDs after rapid testing among men, including MSM, may not be generalizable, and we did not ask questions about disinhibition in this study. However, we think that the potential for disinhibition after receiving a negative test result is important to consider in future research, especially as the use of rapid tests expands in outreach settings.

We found no consistent differences in the effects of the 2 interventions on sexual risk behavior overall or within gender subgroups, despite finding some differences in STD incidence by intervention group. Participants in both intervention groups developed an individualized risk-reduction plan as part of the intervention. Because the interventions did not promote the same risk-reduction plan among all participants, we are not surprised that we did not detect differences in sexual risk behavior by group. Fur-

TABLE 4. Sexual Behavior Reported at the 3-Month Visit by Intervention Group and Gender

Behavior During Past 3 Months	Intervention Group		
	Rapid* (%)	Standard† (%)	Relative Risk (95% CI)
All participants (rapid, n = 1259; standard, n = 1236)			
≥2 sex partners	33.7	30.3	1.11 (0.99–1.25)
Any unprotected sex	64.2	62.5	1.03 (0.97–1.09)
Any unprotected sex with nonprimary partner	18.7	15.8	1.18 (0.99–1.41)
Any unprotected sex while drunk or high	23.7	22.2	1.07 (0.92–1.23)
Sex with new partner on day first met	6.7	7.4	0.90 (0.67–1.20)
One-time sex partner	20.1	18.7	1.07 (0.91–1.26)
Women (rapid, n = 600; standard, n = 583)			
≥2 sex partners	28.5	23.2	1.23 (1.01–1.49)
Any unprotected sex	68.4	64.1	1.07 (0.98–1.16)
Any unprotected sex with nonprimary partner	16.1	13.6	1.18 (0.89–1.56)
Any unprotected sex while drunk or high	24.6	21.0	1.17 (0.94–1.45)
Sex with new partner on day first met	2.7	4.0	0.68 (0.36–1.27)
One-time sex partner	13.0	11.9	1.09 (0.80–1.48)
MSM (rapid, n = 72; standard, n = 71)			
≥2 sex partners	54.9	55.1	1.00 (0.74–1.35)
Any unprotected sex	49.3	37.7	1.31 (0.89–1.92)
Any unprotected sex with nonprimary partner	16.9	19.1	0.88 (0.43–1.80)
Any unprotected sex while drunk or high	22.5	13.0	1.73 (0.82–3.64)
Sex with new partner on day first met	36.6	39.1	0.94 (0.61–1.43)
One-time sex partner	43.7	43.5	1.00 (0.69–1.46)
Men, no male partners (rapid, n = 583; standard, n = 579)			
≥2 sex partners	36.6	34.3	1.07 (0.91–1.25)
Any unprotected sex	61.7	64.0	0.96 (0.88–1.06)
Any unprotected sex with nonprimary partner	21.4	17.5	1.22 (0.96–1.56)
Any unprotected sex while drunk or high	22.8	24.6	0.93 (0.75–1.15)
Sex with new partner on day first met	6.9	6.9	1.00 (0.65–1.54)
One-time sex partner	24.4	22.4	1.09 (0.88–1.35)

*Rapid-test intervention.
†Standard-test intervention.
CI = confidence interval; STD =sexually transmitted disease; MSM = men who had sex with men.

thermore, as STD risk is determined by the interrelationship of risk behaviors as well as the STD prevalence among partners, single risk behaviors may not correlate well with STD or HIV risk.[23–30]

Our study considered only 1 method of providing prevention counseling at the time of rapid HIV testing. Some clients may benefit from additional counseling after they receive their HIV test result. Because it may be difficult to persuade clients to return for an additional counseling session once they know their HIV test result, additional counseling could be given by phone. Clients and staff may find that 1 counseling session after the test, instead of counseling before and after the test (like done in this study), is more convenient and efficient. The efficacy of these other methods of prevention counseling has not been evaluated. Before implementation of new methods, we recommend that they be evaluated by comparing them with methods that have been shown to be effective.

Our study has several strengths. It was a large randomized, controlled trial that measured both STD incidence and behavior and included men and women. Almost 70% of participants were black or Hispanic, the racial and ethnic groups with the highest incidence of HIV infection, and was done in STD clinic attenders, a population that has a relatively high risk of acquiring HIV and STDs. The measurement of STD incidence was more rigorous than in some other studies[27,31] because all participants were screened for STDs at enrollment (enabling us to exclude prevalent STDs that were not acquired during the follow-up period) and participants were routinely screened for STDs at follow-up visits (enabling us to detect asymptomatic STDs).[32] In addition, the follow-up period was longer than that of several other intervention trials,[33,34] enabling us to measure the longer-term effects of the interventions. Finally, behavioral outcomes were collected using ACASI, a method of data collection that reduces interviewer bias and has been shown to be associated with greater disclosure of socially undesirable risk behavior than in-person interviews.[35–43]

Our study also has some limitations. First, we enrolled 20% fewer participants than we had planned to enroll. The STD incidence in the standard-test group was higher than that used in our sample size calculations, so the reduction in sample size did not result in less power than we had expected. Second, the research process may have altered the effectiveness of the interventions. At the enrollment visit, participant fatigue resulting from the ACASI questionnaire may have limited the effectiveness of counseling. This may have had greatest effect on the rapid-test group because they received all their counseling during the enrollment visit. Also, responding to an ACASI questionnaire at each visit may have had an intervention effect that obscured differences in the effects of the study interventions. Third, STD incidence may not accurately reflect the risk for HIV infection.[44–46] Fourth, we are likely to have failed to detect some STDs because over 20% of participants did not return at each follow-up visit. However, because return rates were similar for both groups, the number of STDs missed should be similar for both groups. Fifth, some incident STDs may have been false-positive results because when prevalence is low, the predictive value of a positive test result is low even when highly specific tests are used.[47] STD measurement errors are likely to have occurred with a similar frequency in both intervention groups

and so may have made the effects of the interventions appear more similar than they truly are.

The generalizability of our findings to other settings and to nonresearch situations may be limited. Our study focused on testing and counseling in STD clinics, a setting where prevention counseling has been shown to be of benefit.[3,48] However, the generalizability of our findings to STD clinic clients in nonresearch situations may be limited because those who declined to participate may have differed in important respects from those who enrolled (eg, concern about their risk of acquiring HIV and STDs, willingness to be tested for HIV, and receptiveness to prevention counseling interventions). Also, return rates for the second session in the standard-test group were higher than they would have been under nonresearch conditions. This may have increased the overall effectiveness of the standard-test intervention, making the rapid-test intervention appear relatively less effective by comparison than it would be under nonresearch conditions. Because all participants in our study were given counseling with HIV testing, the results do not provide information on the relative efficacy of rapid and standard HIV testing in settings where testing is done without counseling such as some outreach settings. This study also does not provide information on the effects of testing and counseling with a rapid test compared with no intervention, or the effects of rapid HIV testing and counseling compared with rapid HIV testing alone.

Using rapid HIV testing instead of standard HIV testing has some definite programmatic advantages. With the recent licensure of a simpler and more accurate rapid HIV test,[49,50] the use of rapid HIV tests is likely to increase. The greater convenience of completing testing in 1 visit is likely to increase testing among those at high risk who have not sought testing in the past and increase the proportion of those tested that receive their test result. These factors are likely to increase the proportion of persons with HIV infection who know that they are infected. Early diagnosis enables early treatment and may reduce transmission because persons who are aware of their infection change their behavior.[51] The overall similarity in STD incidence and behavior after rapid testing compared with standard testing favors the use of rapid HIV testing in settings with a high prevalence of HIV infection and a low rate of return for test results. In other settings, the most effective counseling and testing strategy is less straightforward, particularly for men. Further research is needed on the potential for disinhibition of risk-taking behavior after rapid testing with a negative result.

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