Original Investigation

Effect of Risk-Reduction Counseling With Rapid HIV Testing on Risk of Acquiring Sexually Transmitted Infections
The AWARE Randomized Clinical Trial

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IMPORTANCE To increase human immunodeficiency virus (HIV) testing rates, many institutions and jurisdictions have revised policies to make the testing process rapid, simple, and routine. A major issue for testing scale-up efforts is the effectiveness of HIV risk-reduction counseling, which has historically been an integral part of the HIV testing process.

OBJECTIVE To assess the effect of brief patient-centered risk-reduction counseling at the time of a rapid HIV test on the subsequent acquisition of sexually transmitted infections (STIs).

DESIGN, SETTING, AND PARTICIPANTS From April to December 2010, Project AWARE randomized 5012 patients from 9 sexually transmitted disease (STD) clinics in the United States to receive either brief patient-centered HIV risk-reduction counseling with a rapid HIV test or the rapid HIV test with information only. Participants were assessed for multiple STIs at both baseline and 6-month follow-up.

INTERVENTIONS Participants randomized to counseling received individual patient-centered risk-reduction counseling based on an evidence-based model. The core elements included a focus on the patient's specific HIV/STI risk behavior and negotiation of realistic and achievable risk-reduction steps. All participants received a rapid HIV test.

MAIN OUTCOMES AND MEASURES The prespecified outcome was a composite end point of cumulative incidence of any of the measured STIs over 6 months. All participants were tested for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Treponema pallidum* (syphilis), herpes simplex virus 2, and HIV. Women were also tested for *Trichomonas vaginalis*.

RESULTS There was no significant difference in 6-month composite STI incidence by study group (adjusted risk ratio, 1.12; 95% CI, 0.94-1.33). There were 250 of 2039 incident cases (12.3%) in the counseling group and 226 of 2032 (11.1%) in the information-only group.

CONCLUSION AND RELEVANCE Risk-reduction counseling in conjunction with a rapid HIV test did not significantly affect STI acquisition among STD clinic patients, suggesting no added benefit from brief patient-centered risk-reduction counseling.

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In the United States, approximately 1.1 million people are estimated to be living with human immunodeficiency virus (HIV) infection.[1] The incidence of HIV infection is considered to have remained steady over the last decade, with about 50 000 new infections occurring annually.[2] About 1 in 5 people living with HIV is thought to be undiagnosed.[3] The National HIV/AIDS Strategy has a goal of increasing the percentage of people living with HIV who know their status from 79% in 2010 to 90% by 2015.[4] The US Preventive Services Task Force recently recommended that all persons aged 15 to 65 years be screened for HIV.[5] The Centers for Disease Control and Prevention (CDC) issued similar guidelines in 2006, recommending screening for HIV in patients aged 13 to 64 years, unless the prevalence of undiagnosed HIV infection in the patient population is documented to be less than 0.1%.[6]

A major issue regarding scaling up HIV testing is the effectiveness of HIV risk-reduction counseling at the time of testing. Counseling has played a major role in the testing process but involves considerable time, personnel, and financial costs.[7] An earlier study of counseling efficacy, Project RESPECT,[8] showed that patient-centered counseling delivered with HIV testing reduced the incidence of sexually transmitted infections (STIs). The 2008 systematic review of behavioral interventions to reduce STIs (including HIV) for the US Preventive Services Task Force cited Project RESPECT as the only study of moderate-intensity counseling with HIV testing to show an effect on subsequent STI acquisition.[9] However, RESPECT was conducted almost 20 years ago, before the advent of rapid HIV testing and highly effective antiretroviral therapy, and did not include men who have sex with men (MSM), who account for nearly two-thirds of new infections in the United States.[10]

ACASI *audio computer-assisted self-interview*

HSV-2 *herpes simplex virus 2*

MSM *men who have sex with men*

STI *sexually transmitted infection*

We conducted a randomized clinical trial to assess the effectiveness of counseling in reducing STI incidence among sexually transmitted disease (STD) clinic patients. We hypothesized that STI incidence among participants offered an HIV test with counseling would differ from that among participants offered an HIV test with information only.

Methods

Project AWARE recruited individuals seeking services at STD clinics from April 2010 to December 2010. We assessed cumulative STI incidence and sexual risk behaviors during the 6 months after participants were randomized in equal proportions to receive either (1) rapid HIV testing with brief patient-centered risk-reduction counseling or (2) rapid HIV testing with information only. After providing written informed consent, participants were tested for STIs, completed a risk behavior assessment using audio computer-assisted self-interview (ACASI), and were randomized to 1 of the 2 study groups. At 6 months after randomization, participants were tested for incident STIs and completed a follow-up ACASI to measure changes in their self-reported sexual risk. Medical records were abstracted to document any STIs and associated treatment that occurred between the baseline and 6-month assessments. Follow-up was completed in July 2011 and data were locked in January 2012.

Ethical Approval and Protocol Participation

Sites included 9 STD clinics in the following cities: Pittsburgh, Pennsylvania; Jacksonville, Florida; Los Angeles, California; Miami, Florida; Portland, Oregon; Seattle, Washington; Columbia, South Carolina; San Francisco, California; and Washington, DC. The protocol was reviewed and approved by local institutional review boards at all sites.

Participants were eligible if they (1) were seeking services at the STD clinic; (2) were 18 years or older; (3) reported negative or unknown HIV status; (4) could communicate in English; (5) agreed to be tested for STIs including HIV; (6) signed a medical record release to permit abstraction of STI tests, results, and treatment; and (7) lived in the vicinity of the clinic. Participants were reimbursed for their time and effort up to a maximum of $90. Oral informed consent was obtained for screening; eligible individuals provided written informed consent to enroll in the trial.

Randomization

A data coordinating center generated a permuted block randomization scheme stratified by site, race/ethnicity, and gender/partner gender to ensure balance on these factors. Research assistants entered a participant's stratification information using an interactive telephone voice-response system, and a computer revealed the random assignment and generated documentation of the participant's assignment to 1 of the 2 intervention groups.

Interventions

HIV Test With Counseling

Participants in the counseling group received a rapid HIV test and individual patient-centered risk-reduction counseling from persons trained to deliver the RESPECT-2 study counseling model.[11] The counseling included a discussion of the patient's specific HIV/STI risk behaviors and negotiation of achievable risk-reduction steps. Discussions may have included but were not limited to unprotected sex with multiple partners, increased sexual risk taking due to heavy substance use, and lack of discussion of HIV status with sexual partners. The counselor then elicited from the patient a concrete, realistic plan that the patient committed to implement. Additional elements included an explanation of the rapid HIV testing process, including the test's window period, and interpretation of the test findings. Patients were offered the test kit's patient information pamphlet.

After a plan for risk reduction was developed, the OraQuick Advance Rapid HIV-1/2 Antibody test was performed on finger-stick blood. Results were presented after completion, which took approximately 20 to 40 minutes. When disclosing nonreactive results, the counselor monitored the response of the participant; repeated information regarding the window period of the test; went over the risk-reduction plan

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for the participant; and offered any necessary referrals, lubricant, and condoms. When disclosing reactive test results, counselors provided posttest counseling about the meaning of the test results and the need to avoid behaviors that pose a risk for transmission to others. Blood was drawn for a confirmatory test and follow-up arranged to provide the results. Patients with confirmed positive results were linked to HIV primary care. Counselors only conducted the HIV testing with provision of counseling (or information only in the other group) and were not blinded to group assignment. Medical clinicians conducted all other STI testing, and STI testing at follow-up, and were not told patients' group assignment.

HIV Test With Information Only

Participants in the information-only group received a rapid HIV test and information provided verbally about HIV as given in the CDC recommendations.[6] The information provided involved a description of the rapid testing process, as well as the timing and interpretation of test findings, and information on the test's window period. Patients were also asked if they had any questions about the HIV test or process and provided with the test kit's patient information pamphlet. After the OraQuick Advance Rapid HIV-1/2 Antibody test was administered using finger-stick blood, participants waited 20 to 40 minutes for the test findings. Nonreactive results were provided by counselors, who repeated information about the test's window period. With reactive test results, counselors followed the same procedure as described for the counseling group.

Intervention Fidelity

Counselors provided the research interventions in both study groups. All interventions were audiotaped with the consent of the participants, and 10% of the audiotapes were randomly reviewed during the trial to provide feedback to counselors and ensure the interventions were delivered as designed. Required activities, such as assessing risk and contributing factors and providing information about the rapid test, were rated using a 4-point scale: 0, not at all; 1, somewhat; 2, mostly; and 3, completely. Median ratings between 1.5 and 2.5 were classified as good, and those greater than or equal to 2.5 were classified as excellent. Rates of agreement and κ statistics were calculated across 3 raters.

Measures

Cumulative STI Incidence

At baseline and 6-month follow-up, all participants underwent serological testing for syphilis, herpes simplex virus 2 (HSV-2), and HIV. Male urine specimens were tested for *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT). Rectal swabs were also obtained from MSM and tested for GC and CT. Vaginal swabs were tested for GC, CT, and *Trichomonas vaginalis* (TV). Aptima Combo-2 (Gen-Probe Diagnostics) was used to test for GC and CT, and the Gen-Probe TV Analyte Specific Reagent was used to test for TV. Serologic tests for syphilis involved initial testing with either rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL) test; if those results were positive, treponema pallidum particle agglutination (TPPA) assay or fluorescent treponemal antibody-absorption (FTA-ABS) tests were performed. Positive syphilis results were interpreted by a committee of clinicians/investigators, blinded to participants' study group, taking into account physical findings, symptoms, known exposures to syphilis, and historical serological test results. Infection with HSV-2 was evaluated using the HerpeSelect enzyme-linked immunosorbent assay (Focus Diagnostics); specimens with index values of 0.9 to 3.5 underwent confirmatory testing by Western blot, with results regarded as definitive.[12] To conserve resources, stored serum specimens obtained at baseline were tested for HSV-2 only if 6-month follow-up specimens were positive or if participants were lost to follow-up.

Medical records abstraction was performed to ascertain any STI diagnoses that occurred between randomization and 6-month follow-up. Patients who had negative test results for a particular STI at baseline were considered an incident case for that STI if they had positive results at 6 months or medical records showed they had positive results for that STI at any time after baseline. Patients who had positive results for a particular STI at baseline were considered an incident case only if tested positive for that STI after adequate treatment. Cases of HSV-2, HIV, or both were only considered incident STIs in patients who had negative results at baseline. A patient with an incident diagnosis of any of the measured STIs counted as positive for cumulative STI incidence. To be considered negative for cumulative STI incidence, a patient had to have negative results on all the measured STIs at the 6-month assessment and no interim STI diagnosis in the medical record since the baseline visit. Patients were retested if their samples were lost or subject to laboratory error. If a patient returned for retesting more than 30 days after randomization for a particular STI test, the result for that particular STI was considered missing at baseline. Similarly, if patients did not have a test for a particular STI more than 145 days after baseline, the result for that STI was considered missing at follow-up.

Sexual Risk Behaviors and Gender

Sexual risk behaviors during the prior 6 months, assessed at baseline and 6-month follow-up using ACASI, included the number of unprotected anal or vaginal sexual episodes, unprotected sex with primary and nonprimary partners, sexual acts with substance use, total number of partners, and number of unprotected partners.[13-16]

For the purpose of planned subgroup analyses, participants were categorized as male if they reported themselves to be male. Individuals reporting themselves as transgender were grouped with men if they had a penis because of the commonality of potential risk behaviors. Men were classified as MSM if, at study intake, they reported any previous anal or oral sex with males or if on the ACASI sexual risk behavior questions they reported having anal or oral sex with another male at any time during the study. All men who did not meet the definition of MSM were classified as men who have sex with women (MSW). Women were not categorized by the gender of their partners; not all female participants had only male partners (ie, 67 women reported only female partners, and 145 women reported both male and female partners).

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Safety

Deaths and adverse events that were considered to be related to the intervention by participants or investigators were reported to the medical monitor and the data and safety monitoring board.

Statistical Analysis

All analyses were conducted using SAS version 9.3 (SAS Institute). Logistic regression and Wilcoxon rank sum tests were used to compare baseline STI rates and sexual risk behaviors, respectively, by participant and partner gender group. All study group comparisons were conducted on an intent-to-treat basis with all patients included as randomized. The primary outcome, behavior outcomes, and test of interaction effects were considered statistically significant at the nominal α level of .05 using 2-sided tests.

The primary outcome was cumulative STI incidence (yes/no) during 6 months tested using logistic regression including treatment group, baseline STI prevalence, site, and randomization stratum. Participants were randomized before HIV testing and were included in analyses regardless of their baseline HIV status. Additional post hoc tests excluded participants who were HIV-positive at baseline because all HIV-positive individuals received posttest counseling and a separate analysis tested for the presence of a site-by-treatment interaction on cumulative STI incidence. For the STI outcomes, Mantel-Haenszel adjusted risk ratios (aRRs) are also presented.

Behavior outcomes included the total number of unprotected sex acts as well as the number of unprotected sex acts with primary and nonprimary partners, number of partners, and the number of partners with whom the participant had unprotected sex. Analyses of these sexual risk behaviors used zero-inflated negative binomial regressions including treatment group, baseline level of the risk behavior, site, and randomization stratum. The adjusted incidence rate ratios (IRRs) from these models are presented. For both the STI outcome and behavior outcomes, additional preplanned tests of interaction were conducted to examine subgroups: participant and partner gender (MSW, MSM, and women) by treatment group, age (<25 vs ≥25 years) by treatment group, and race/ethnicity (black, Hispanic, white, other) by treatment group. For significant interaction effects in the case of participant and partner gender, all pairwise comparisons were investigated, wherein statistical significance required an α of .017 (.05/3). If there was no significant interaction, main effects of subgroup were examined.

Missing laboratory records for one of the STI measures caused missing data for 362 of 5012 patients (7.2%) on baseline STI prevalence or cumulative STI incidence. According to our statistical analysis plan, multiple imputations were used to account for missing data because these missing data exceeded 5%. All counts and denominators presented are based on observed data; however, in the statistical tests of all hypotheses and calculation of the presented risk ratios, we used multiple imputations of data sets with all 5012 cases. Twenty imputed data sets were generated. Imputations were conducted separately by intervention group and for participant and partner gender group and then combined as recommended to preserve interactions.[17] Data were imputed using Markov chain Monte Carlo methods for nonmonotone missing data as implemented in SAS version 9.3. All variables analyzed in any analysis were included in the imputation model. Imputed data for the baseline STI prevalence and cumulative STI incidence were rounded to 0 or 1 using a method described by Bernaards et al.[18] Mantel-Haenszel aRRs from each imputed sample were log-transformed, estimates combined, and then back-transformed.[19]

Simulations done in SAS version 9.1.3 showed that 1663 participants per intervention group or a 3326 total sample at the 6-month assessment was required to provide more than 80% power for both a 3.2 percentage point risk difference associated with treatment overall as found in the original RESPECT trial and also an interaction among participant and partner gender groups in which the ratio of risk ratios between MSM and participants with opposite-gender partners is approximately 2. A conservative assumption of 70% retention resulted in a planned randomization of 5000 participants.

Cost Analysis

We applied microcosting methods[20] to determine each clinic's costs for rapid HIV testing and counseling, excluding research-related costs. Costs were designated as start-up (equipment and training), variable- and time-dependent (eg, weekly costs, ongoing staff time, materials, inventory management, quality assurance, and training), or overhead (eg, additional space requirements) in each clinic (see the eMethods in the Supplement). We applied national labor rates[21]and rapid test costs.[22] All costs are reported in 2010 US dollars from the clinic perspective. For each study group, we calculated clinic costs for start-up and for delivering the intervention (mean cost per patient tested and mean cost per newly identified HIV infection).

Results

Study personnel made 14 948 approaches to STD clinic patients for participation. The number of approaches constitutes an upper bound on the number of individuals who were approached because personally identifiable information was not collected prior to obtaining consent to be screened, preventing identification of individuals who were approached multiple times. Of the 6239 people consenting to be screened, 5028 were eligible (80.6%) and 5012 (99.5% of those eligible) were randomized. Numbers of participants randomized at individual study sites ranged from 484 to 600. Reasons for ineligibility and subject flow are presented in the CONSORT flowchart (**Figure**). The 6-month retention rate was 86.9%. Baseline demographic characteristics, STI prevalence, and reported sexual risk behaviors were similar for the counseling and information-only groups (**Table 1**). Prevalence of any STI at baseline was highest among women; MSM reported fewer unprotected sex acts and unprotected partners than did MSW or women. Prevalence of baseline STI and sexual risk behavior by participant/partner gender are reported in **Table 2**.

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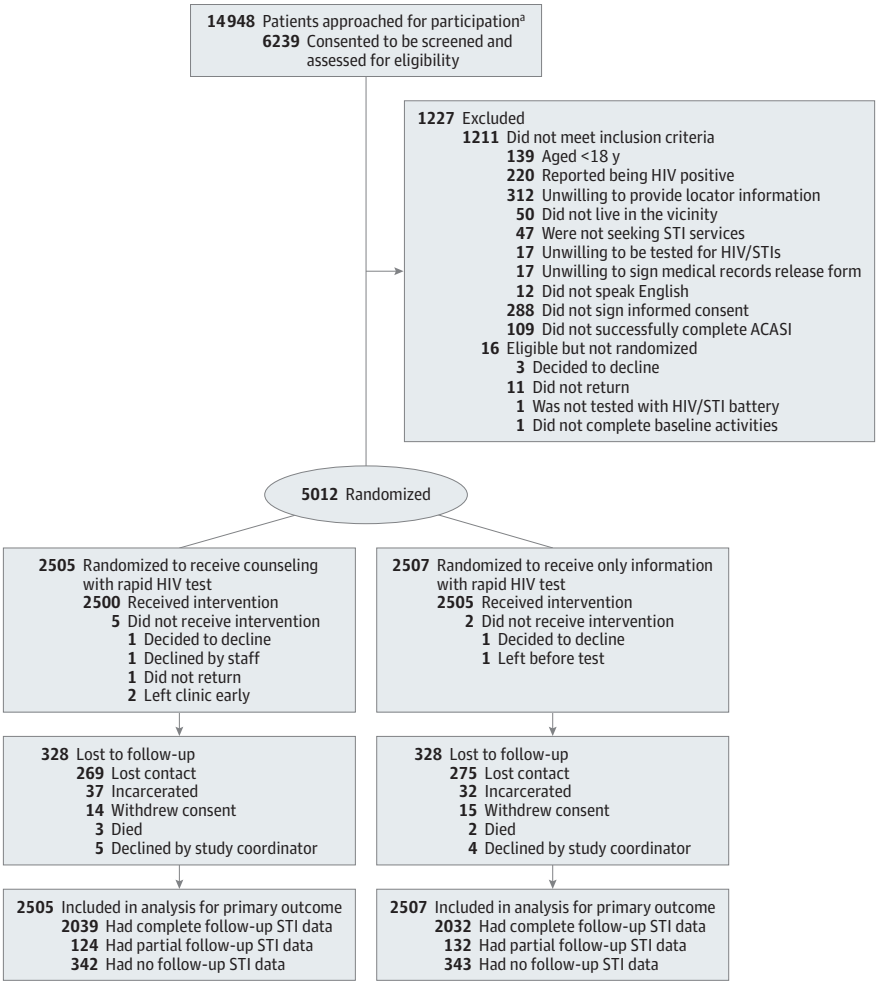
Figure. Study Flow Diagram



ACASI indicates audio computer-assisted self-interview; HIV, human immunodeficiency virus; STI, sexually transmitted infection. [a]Included patients approached multiple times.

Cumulative STI Incidence

Cumulative STI incidence was 250 of 2039 (12.3%) in the counseling group and 226 of 2032 (11.1%) in the information-only group (aRR, 1.12; 95% CI, 0.94-1.33) (**Table 3**). This pattern was consistent at all sites ($F_{8,4602}$ = 0.23, P < .99). Excluding participants who were HIV-positive at baseline, cumulative STI incidence was 246 of 2024 (12.2%) in the counseling group and 219 of 2012 (10.9%) in the information-only group (aRR, 1.13; 95% CI, 0.95-1.34). There were 730 of 5012 patients (14.6%) who had at least 1 interim visit according to medical records, and 86 of 476 patients (18.1%) with positive cumulative STI incidence were identified based on interim STI before 6-month follow-up.

Heterosexual and MSM Subgroup Analyses

The STI incidence differed by study group in interaction analyses for the 3 subgroups of MSM, MSW, and women ($F_{2,1034}$ = 3.22, P < .04) (Table 3). In the counseling group, 99 of 529 MSM (18.7%) had an incident STI compared with 68 of 545 MSM (12.5%) in the information-only group (aRR, 1.41; 98.3% CI, 1.05-1.90). The STI incidence was not significantly different in the counseling and information-only groups for women (aRR, 1.07; 98.3% CI, 0.79-1.43) or MSW (aRR, 0.81; 98.3% CI, 0.50-1.31). There were 2 incident cases of HIV in women, 1 in each study group. The remaining 12 incident cases of HIV were in MSM: 4 in the counseling group and 8 in the information-only group (overall aRR, 0.57; 95% CI, 0.19-1.73).

Other Subgroup Analyses

There were no significant differences in interaction analyses in cumulative STI incidence between the counseling and information-only groups by age group (t_{843} = 1.13, P < .26) or race/ethnicity ($F_{3,1597}$ = 0.18, P < .91) (Table 3). Participants younger than 25 years of age had higher cumulative STI incidence (204/1258, 16.2%) than did those 25 years and older (263/2707, 9.7%; aRR, 1.67; 95% CI, 1.40-1.99). Black participants had higher cumulative STI incidence (232/1655, 14.0%) than white participants (101/1251, 8.1%; aRR, 1.56; 95% CI, 1.15-2.11). There was neither a direct effect (t_{251} = 1.54, P < .13) nor an interaction effect (t_{353} = 0.45, P < .66) of reporting the use of substances before sex during the 6 months before baseline.

Sexual Risk Behaviors

There was no significant effect of counseling on either the overall number of unprotected sex acts (Table 3) or unprotected sex

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Table 1. Baseline Characteristics by Study Group

	Rapid HIV Test With Counseling (n = 2505)[a]	Rapid HIV Test With Information Only (n = 2507)[a]
Age, No. (%)		
<25 y	1705 (68.1)	1727 (68.9)
≥25 y	800 (31.9)	780 (31.1)
Male sex, No. (%)	1655 (66.1)	1653 (65.9)
MSM, No. (%)	689 (27.5)	711 (28.4)
Race/ethnicity, No. (%)		
Black	1045 (41.7)	1053 (42.0)
Hispanic	382 (15.2)	385 (15.3)
White	798 (31.9)	794 (31.7)
Other	280 (11.2)	275 (11.0)
STIs, No./total No. (%)		
Any STI	1049/2412 (43.5)	1092/2419 (45.1)
Any STI excluding trichomoniasis	1016/2413 (42.1)	1070/2423 (44.2)
Gonorrhea	137/2430 (5.6)	145/2431 (6.0)
Chlamydia	238/2434 (9.8)	254/2436 (10.4)
Trichomoniasis	126/837 (15.1)	119/842 (14.1)
Syphilis	28/2475 (1.1)	35/2495 (1.4)
HSV-2	758/2492 (30.4)	793/2494 (31.8)
HIV	29/2502 (1.2)	24/2504 (1.0)
Sexual risk behaviors prior 6 mo, predicted mean (95% CI)[b]		
No. of sex acts	34.6 (32.6-36.8)	33.4 (31.4-35.5)
No. of unprotected sex acts	23.9 (22.1-25.9)	22.6 (20.9-24.4)
No. of partners	4.7 (4.4-4.9)	4.6 (4.4-4.9)
No. of unprotected partners	2.1 (2.0-2.3)	2.1 (2.0-2.2)

Abbreviations: HIV, human immunodeficiency virus; HSV-2, herpes simplex virus 2; MSM, men who have sex with men; STIs, sexually transmitted infections.

[a] Randomized sample size. Denominators differ because of missing data. Denominator for trichomoniasis does not include men.

[b] From negative binomial regression estimated on observed data.

acts with a primary partner. Participants in the counseling group did report lower rates of unprotected sex with nonprimary partners (IRR, 0.66; 95% CI, 0.55-0.79). Counseling group participants reported lower numbers of total partners than did information-only participants (IRR, 0.81; 95% CI, 0.75-0.87); there were no significant differences in number of unprotected partners (Table 3). Because higher incidence of STI in the counseling group relative to the information-only group was observed among MSM, we explored sexual risk behaviors among MSM. The MSM who received counseling reported lower numbers of unprotected partners (IRR, 0.71; 95% CI, 0.61-0.83) but not lower numbers of total partners (IRR, 0.91; 95% CI, 0.80-1.03) compared with MSM in the information-only group. The MSW and women reported no difference in the number of unprotected partners by intervention group (IRR, 1.06; 95% CI, 0.96-1.17) but did report a reduction in total partners (IRR, 0.76; 95% CI, 0.69-0.84) in the counseling group compared with the information-only group. There were no interactions of MSM status with any of the other sexual risk indicators examined.

Intervention Duration and Fidelity

In the counseling group, the median duration of a counseling session was 28 minutes (interquartile range [IQR], 23-38), and median duration of a results session was 7 minutes (IQR, 5-11). In the information-only group, the median duration of an information-only session was 3 minutes (IQR, 2-4), and median duration of a results session was 3 minutes (IQR, 1-3). In the counseling group, 222 of 244 sessions (91.0%) were rated as excellent and 15 of 244 (6.1%) as good. In the information-only group, 231 of 262 sessions (88.2%) were rated as excellent and 31 of 262 (11.8%) as good. Rates of agreement for the information-only group were 100% (κ could not be calculated) and 95.9% for the counseling group (κ ranged from 0.72 to 0.78).

Adverse Events

There were 13 nonserious adverse events in the counseling group and 5 in the information-only group, all associated with specimen collection (eg, syncope, pain at finger-stick site). None of the 3 deaths in the counseling group or 2 deaths in the information-only group were related to study procedures.

Cost Analysis

For the counseling and information-only groups, median startup costs were $25 706 per site (range, $20 938-$29 446) and $471 per site (range, $328-$1801), respectively. The average cost per patient tested in the counseling group was $56 (range, $40-$75), consisting of $29 in variable costs, $10 in time-dependent costs, and $17 in overhead costs. The average cost per patient tested for the information-only group was $23 (range, $18-$28), consisting of $16 in variable costs, $3 in time-dependent costs, and $4 in overhead costs. Based on the baseline visit, the average cost per newly identified HIV infection (n = 53) was $5296 (range, $3783-$7092) for the counseling group and $2175 (range, $1702-$2648) for the information-only group.

Discussion

Despite the historical emphasis on risk-reduction counseling as integral to the HIV testing process, no contemporary data exist on the effectiveness of such counseling. The results of Project AWARE help fill this gap. Brief counseling at the time of HIV testing was not effective for reducing new STIs during the subsequent 6 months among persons at risk for HIV. Analyses by age group, race/ethnicity, and gender (for heterosexuals) demonstrated no significant effect of counseling on STI rates in any of these several important subgroups.

The finding that MSM who received counseling acquired more incident STIs is of concern. However, 4 incident HIV infections occurred in MSM in the counseling group and 8 in the information-only group, a statistically nonsignificant finding but one that suggests future areas for research on the effects of both counseling and behaviors after negative HIV test re-

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Table 2. Baseline STI and Sexual Risk Behavior by Participant/Partner Gender[a]

	MSW (n = 1908)[b]	MSM (n = 1400)[b]	Women (n = 1704)[b]	*P* Value MSW vs MSM[c]	*P* Value MSW vs Women[c]	*P* Value MSM vs Women[c]	Overall (N = 5012)[b]
STIs, No./total No. (%)							
Baseline STI	718/1874 (38.3)	504/1292 (39.0)	919/1665 (55.2)	<.70	<.001	<.001	2141/4831 (44.3)
Baseline STI, excluding trichomoniasis	718/1874 (38.3)	504/1292 (39.0)	864/1670 (51.7)	<.34	<.001	<.001	2086/4836 (43.1)
Gonorrhea	97/1892 (5.1)	134/1287 (10.4)	51/1682 (3.0)	<.001	<.002	<.001	282/4861 (5.8)
Chlamydia	182/1887 (9.6)	165/1299 (12.7)	145/1684 (8.6)	<.007	<.29	<.001	492/4870 (10.1)
Trichomoniasis	NA	NA	245/1679 (14.6)				NA
Syphilis	8/1895 (0.4)	47/1391 (3.4)	8/1684 (0.5)	<.001	<.81	<.001	63/4970 (1.3)
HSV-2	523/1903 (27.5)	271/1391 (19.5)	757/1692 (44.7)	<.001	<.001	<.001	1551/4986 (31.1)
HIV	9/1905 (0.5)	38/1397 (2.7)	6/1704 (0.4)	<.001	<.58	<.001	53/5006 (1.1)
Sexual risk behaviors prior 6 mo, predicted mean (95% CI)[d]							
No. of sex acts	36.2 (33.8-38.9)	27.3 (25.1-29.6)	37.2 (34.5-40.1)	<.19	<.14	<.003	34.0 (32.5-35.5)
No. of unprotected sex acts	25.7 (23.5-28.1)	16.8 (15.1-18.6)	26.1 (23.7-28.7)	<.001	<.01	<.001	23.3 (22.0-24.6)
No. of partners	3.0 (2.9-3.2)	7.0 (6.6-7.4)	4.5 (4.3-4.8)	<.001	<.97	<.001	4.6 (4.5-4.8)
No. of unprotected partners	1.6 (1.5-1.8)	3.3 (3.1-3.5)	1.7 (1.6-1.8)	<.001	<.62	<.001	2.1 (2.0-2.2)

Abbreviations: HIV, human immunodeficiency virus; HSV-2, herpes simplex virus 2; MSM, men who have sex with men; MSW, men who have sex with women; NA, not applicable; STI, sexually transmitted infection.

[a] Women may have had sex with either females, males, or both. MSM had sex with men and may have also had sex with women. MSW were men who only had sex with women.

[b] Randomized sample size. Denominators differ because of missing data. Denominator for trichomoniasis does not include men.

[c] *P* values for STIs are based on logistic regression; *P* values for sexual risk behaviors are based on negative binomial regression.

[d] From negative binomial regression with no covariates.

sults among MSM, including qualitative and quantitative studies of risk and protective behaviors such as serosorting and other negotiated safety strategies.[23-25]

Analyses of sexual risk behavior demonstrated some reduction in risk behaviors in the counseling group compared with the information-only group, despite no difference in STI incidence. It is possible that the magnitude or nature of the behavior change was insufficient to reduce STI incidence. This finding might also be due to a bias of counseling-group participants to report greater reductions in risk behaviors than truly occurred because of the counseling intervention or because the primary measures of behavior change were insufficiently linked to disease transmission in STI transmission networks. These findings are consistent with the results of other randomized controlled trials in which reported risk behavior reductions were not associated with significantly reduced disease incidence[26-28] and highlight the importance of using biological outcomes as a primary outcome for intervention trials. As an example, our research team conducted a study in patients receiving treatment for substance use and found that RESPECT counseling at the time of HIV testing had no effect in reducing self-reported sexual risk behaviors, but the more informative end point of biological outcomes was not available.[29] Studies of more intensive counseling at the time of HIV testing[30] appear promising, but they have not been evaluated using biological outcomes.

We found that start-up costs and costs per test were substantially higher for testing with counseling compared with testing with information only because of higher training costs, additional time requirements, quality assurance activities necessary to maintain fidelity, and associated overhead. Given the lack of observed superiority in outcomes, counseling is an inefficient use of resources in this setting. Our average costs per rapid test were higher than previous estimates[7] because of the inclusion of overhead costs and, for risk-reduction counseling, ongoing training and quality assurance activities. These costs should be considered in future studies of risk-reduction counseling. Compared with a national estimate of $2528 average cost per newly identified HIV-infected individual,[31] costs in this study were approximately 13% lower for the information-only group and more than twice as high for the counseling group.

This study should be interpreted in the light of several limitations. First, we used STI incidence as a surrogate marker for HIV incidence because the sample size necessary for an HIV incidence outcome was impractical. Second, we did not test any patients for pharyngeal gonorrhea or chlamydia, nor did we test for rectal infections in women, and therefore, we cannot assess how such infections might have affected our findings. Third, in this study, brief patient-centered counseling was assessed at the time of an HIV rapid test during 1 clinic visit. Results do not apply to different models of risk-reduction counseling with more sessions or longer duration.[9,32] Fourth, results may not be generalizable to international settings. Finally, participants were only followed up for 6 months, and STI incidence in the two study groups may have been different with

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Table 3. Six-Month STI Incidence and Sexual Risk Behavior by Group

	Rapid HIV Test With Counseling[a]	Rapid HIV Test With Information Only[a]	aRR or IRR (95% CI)[b]
STIs, No./total No. (%)			
Any STI	250/2039 (12.3)	226/2032 (11.1)	1.12 (0.94-1.33)
Gonorrhea	43/2097 (2.1)	40/2097 (1.9)	1.14 (0.73-1.76)
Chlamydia	104/2094 (5.0)	103/2088 (4.9)	1.02 (0.78-1.34)
Trichomoniasis	56/724 (7.7)	53/736 (7.2)	1.14 (0.80-1.62)
HSV-2[c]	53/1492 (3.6)	43/1446 (3.0)	1.19 (0.80-1.77)
Syphilis	12/2142 (0.6)	6/2142 (0.3)	2.22 (0.83-5.94)
HIV[c]	5/2119 (0.2)	9/2122 (0.4)	0.57 (0.19-1.73)
Sexual risk behaviors prior 6 mo, predicted mean (95% CI)[d]			
No. of sex acts	28.6 (26.5-30.9)	29.1 (27.0-31.5)	0.99 (0.90-1.09)
No. of unprotected sex acts	17.4 (15.5-19.4)	18.3 (16.4-20.5)	0.98 (0.86-1.13)
No. of partners	2.7 (2.5-2.8)	3.0 (2.8-3.2)	0.88 (0.82-0.94)
No. of unprotected partners	1.1 (1.0-1.2)	1.1 (1.1-1.2)	0.97 (0.90-1.05)
Subgroup Analysis of STI Incidence			
Participant's and partner gender, No./total No. (%)			
MSM	99/529 (18.7)	68/545 (12.5)	1.41 (1.05-1.90)[e]
MSW only	42/753 (5.6)	49/740 (6.6)	0.81 (0.50-1.31)[e]
Women	104/697 (14.9)	105/701 (15.0)	1.07 (0.79-1.43)[e]
Age, No./total No. (%)			
<25 y	103/638 (16.1)	101/620 (16.3)	1.01 (0.77-1.31)
≥25 y	142/1341 (10.6)	121/1366 (8.9)	1.21 (0.96-1.52)
Race/ethnicity, No./total No. (%)			
Black	119/822 (14.5)	113/833 (13.6)	1.06 (0.83-1.34)
Hispanic	43/304 (14.1)	42/318 (13.2)	1.12 (0.77-1.64)
White	55/633 (8.7)	46/618 (7.4)	1.16 (0.79-1.70)
Other	28/220 (12.7)	21/217 (9.7)	1.06 (0.83-1.34)
Sex acts with substance use, No./total No. (%)			
Sex with substance use	115/952 (12.1)	106/952 (11.1)	1.14 (0.89-1.46)
No sex with substance use	99/839 (11.8)	86/844 (10.2)	1.10 (0.84-1.43)

Abbreviations: aRR, adjusted risk ratio; HIV, human immunodeficiency virus; HSV-2, herpes simplex virus 2; IRR, incidence rate ratio; MSM, men who have sex with men; MSW, men who have sex with women; STI, sexually transmitted infection.

[a] Observed counts are presented. Denominators differ because of missing data. Denominator for trichomoniasis does not include men.

[b] For STI and sex acts with substance use, aRRs were based on Mantel-Haenszel analysis; for count of sexual risk behaviors, adjusted IRRs were from negative binomial regression. Both are estimated on multiply imputed data.

[c] Excludes participants who were positive for this STI at baseline.

[d] From negative binomial regression including baseline level of risk, randomization stratum, and site. Mean model estimated on observed data.

[e] The CI is 98.3% for this subgroup (see "Methods").

longer follow-up. This seems unlikely because in Project RESPECT the maximum effect on STI incidence was observed in the first 6 months.

Overall, these study findings lend support for reconsidering the role of counseling as an essential adjunct to HIV testing. This inference is further buttressed by the additional costs associated with counseling at the time of testing: without evidence of effectiveness, counseling cannot be considered an efficient use of resources. Posttest counseling for persons testing HIV-positive remains essential, both for addressing psychological needs and for providing and ensuring follow-through with medical care and support. A more focused approach to providing information at the time of testing may allow clinics to use resources more efficiently to conduct universal testing, potentially detecting more HIV cases earlier and linking and engaging HIV-infected people in care.

Conclusion

Risk-reduction counseling in conjunction with a rapid HIV test did not significantly affect STI acquisition among STD clinic patients, suggesting no added benefit from brief patient-centered risk-reduction counseling.

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