

Implementing Rapid HIV Testing With or Without Risk-Reduction Counseling in Drug Treatment Centers: Results of a Randomized Trial

Lisa R. Metsch, PhD, Daniel J. Feaster, PhD, Lauren Gooden, PhD, Tim Matheson, PhD, Raul N. Mandler, MD, Louise Haynes, MSW, Susan Tross, PhD, Tiffany Kyle, PhD, Dianne Gallup, PhD, Andrzej S. Kosinski, PhD, Antoine Douaihy, MD, Bruce R. Schackman, PhD, Moupali Das, MD, Robert Lindblad, MD, Sarah Erickson, PhD, P. Todd Korthuis, MD, Steve Martino, PhD, James L. Sorensen, PhD, José Szapocznik, PhD, Rochelle Walensky, MD, Bernard Branson, MD, and Grant N. Colfax, MD

There are approximately 50 000 new HIV infections in the United States each year, with incidence remaining stable between 2006 and 2009.¹ Among the more than 1 million people living with HIV in the United States, approximately one fifth do not know they are infected.² This has led to expanded efforts to increase HIV testing, as recently outlined in the US National HIV/AIDS Strategy.³ In 2006, the Centers for Disease Control and Prevention (CDC) recommended routine HIV screening of all adults and adolescents in health care settings,⁴ with other medical groups following with similar recommendations.^{5,6}

Medical care settings and community-based testing sites are where most testing occurs,⁷ but the CDC and others have called for expanded testing in other locales serving high-risk persons, including drug treatment programs.⁴ Previous studies have shown that, despite high HIV prevalence in drug treatment programs (ranging from more than 3% in noninjection drug users [non-IDUs] to 27% in IDUs^{8,9}) and the well-established link among substance use, sexual risk behaviors, and HIV, fewer than half of US drug treatment programs offer HIV testing on site.¹⁰⁻¹²

The role of risk-reduction counseling in the HIV testing process remains a central question, because of both questions of efficacy in reducing HIV infection rates and its implications for the time and personnel required for the recommended scale-up of testing. In a major policy shift, the 2006 CDC testing guidelines specify that risk-reduction counseling should only be required for persons who test HIV-positive.

In the era of rapid HIV testing, the effectiveness of brief risk-reduction counseling for reducing risk behavior in persons who test HIV-negative is unknown. The seminal US trial,

Objectives. We examined the effectiveness of risk reduction counseling and the role of on-site HIV testing in drug treatment.

Methods. Between January and May 2009, we randomized 1281 HIV-negative (or status unknown) adults who reported no past-year HIV testing to (1) referral for off-site HIV testing, (2) HIV risk-reduction counseling with on-site rapid HIV testing, or (3) verbal information about testing only with on-site rapid HIV testing.

Results. We defined 2 primary self-reported outcomes a priori: receipt of HIV test results and unprotected anal or vaginal intercourse episodes at 6-month follow-up. The combined on-site rapid testing participants received more HIV test results than off-site testing referral participants ($P < .001$; Mantel-Haenszel risk ratio = 4.52; 97.5% confidence interval [CI] = 3.57, 5.72). At 6 months, there were no significant differences in unprotected intercourse episodes between the combined on-site testing arms and the referral arm ($P = .39$; incidence rate ratio [IRR] = 1.04; 97.5% CI = 0.95, 1.14) or the 2 on-site testing arms ($P = .81$; IRR = 1.03; 97.5% CI = 0.84, 1.26).

Conclusions. This study demonstrated on-site rapid HIV testing's value in drug treatment centers and found no additional benefit from HIV sexual risk-reduction counseling. (*Am J Public Health.* 2012;102:1160-1167. doi:10.2105/AJPH.2011.300460)

Project RESPECT¹³ demonstrated that two 20-minute counseling sessions in conjunction with conventional HIV testing for sexually transmitted disease (STD) clinic patients including IDUs¹⁴ significantly increased self-reported condom use and reduced STD incidence. However, in the 15 years since RESPECT, the context for HIV testing has changed dramatically: rapid testing is now widespread, effective treatment has greatly reduced HIV-related morbidity and mortality, and many people report having been tested for HIV at least once.

To examine the efficacy of on-site rapid testing and risk-reduction counseling in increasing receipt of results and reducing HIV risk behaviors in drug treatment program patients, the National Drug Abuse Treatment Clinical Trials Network (CTN) conducted the

HIV Rapid Testing and Counseling Study (CTN 0032). The aims were to quantify the degree to which available on-site rapid HIV testing increases testing and receipt of results, and to determine whether counseling affects testing acceptance and reduces HIV risk behaviors.

METHODS

CTN 0032 was a randomized controlled trial conducted in 12 US community-based drug treatment programs that previously did not offer on-site HIV testing. Participants were randomized to (1) referral for off-site HIV testing, (2) brief, participant-tailored risk-reduction counseling with the offer of an on-site rapid HIV test, or (3) information only (description of the testing procedure) with the offer of an on-site rapid HIV test. Participants

completed audio computer-assisted self-interviews (ACASIs) at baseline, at 1 month post-randomization to determine if they had been tested for HIV and received the results, and at 6 months postrandomization to measure self-reported sexual and injection risk behaviors.

Sites

The trial was conducted from January through December 2009 among patients receiving services at community treatment programs for drug or alcohol abuse in Tucson, Arizona; Plainville and Danbury, Connecticut; Baltimore, Maryland; Cape Girardeau, Missouri; Salisbury, North Carolina; Santa Fe, New Mexico; Portland, Oregon; Pittsburgh, Pennsylvania; Columbia and West Columbia, South Carolina; and Chesterfield, Virginia. Participating programs included outpatient psychosocial, intensive outpatient, outpatient narcotic replacement, and residential programs. All sites obtained approval from an institutional review board.

Research study staff underwent approximately 32 hours of training on topics ranging from good clinical research practices to study procedures and documentation. Counselors received an additional 76 hours of training in the delivery of study interventions.

Participants

Recruiters attempted to approach all patients accessing services. Prospective participants were approached at least once at various times including during intake, and before, after, or between drug treatment services. Those eligible were self-reported HIV-negative (or status unknown) men and women aged 18 years or older, seeking or receiving drug treatment services at the site and had not received results of an HIV test done within the past 12 months. Potential participants had to communicate in English, provide contact information, and sign a medical records release. After providing written informed consent, and before randomization, participants completed the baseline ACASI.

The ACASI included questions on participant demographics, HIV testing history, and, for the 6 months before the interview, sexual behavior (e.g., total number of vaginal and anal sexual partners and protected or unprotected sexual acts), substance use (frequency and

amount of use), and injection risk behavior. Questions also included the Drug Abuse Screening Test (DAST-10).¹⁵

Participants were randomly assigned by study research assistants using an interactive voice response system over telephone to 1 of the 3 intervention groups. The CTN central data and statistics center generated a permuted block randomization scheme stratified by site, race/ethnicity, and gender. The race/ethnicity strata consisted of Hispanics, African Americans, Whites, and other race/ethnicity.

Interventions

The off-site referral group represented standard practice before the study at the participating sites. Participants were offered referrals to HIV testing sites, which included contact information, hours of operation, types of HIV testing, and fees (if any) for each testing agency. These participants received no motivational counseling, no assistance in choosing where or when to get tested, no face-to-face risk assessment, and no risk-reduction counseling.

Participants in the on-site test with counseling group received individual risk-reduction counseling based on that in the RESPECT-2 study,¹⁶ were encouraged to test for HIV, and were offered a rapid HIV test. If the participant declined the rapid HIV test, the counselor inquired about the reason and gently attempted to address the participant's reluctance to be tested. If the participant continued to decline, the counselor accepted this choice. The core elements of RESPECT-2 counseling required approximately 30 minutes and included an orientation to the rapid testing procedure, routes of HIV transmission, interpretation of test results, and an explanation of the testing window period. A personalized examination of risk focused on whatever was salient to the risk behavior of the participant: sexual risks, injection risks, or reducing substance use. Once a risk-reduction plan was created, the counselor offered the rapid HIV test. If the participant accepted, the OraQuick Advance Rapid HIV-1/2 Antibody test (OraSure Technologies, Bethlehem, PA) was administered and the participant waited 20 to 40 minutes for the results. Disclosure of test results for nonreactive tests lasted approximately 10 minutes, during which the counselor provided the test result; evaluated the participant's response;

reiterated the duration of the window period; reviewed the participant's risk-reduction plan; offered referrals for appropriate medical, psychological, and social services as needed; and offered condoms (with demonstration) and lubricant.

Participants in the on-site HIV test with information-only group received verbal information about the rapid HIV test as recommended by the CDC⁴ and were offered a rapid HIV test. They received no motivating information to get tested, no risk assessment, and no risk-reduction counseling. Information included a description of the rapid testing procedure, timing for and meaning of test results, and an explanation of the window period during which an antibody test might be negative. Providing this information took less than 5 minutes. Participants were then offered a rapid HIV test. No further intervention was conducted with participants who declined. Participants who accepted were tested and waited 20 to 40 minutes for the test results. Counselors delivered the test results in less than 5 minutes, again explaining the duration of the window period during which the test might be falsely negative.

In the 2 on-site HIV test arms, a reactive test was followed by a repeat testing using OraQuick whole blood fingerstick test (OraSure Technologies, Bethlehem, PA) to minimize false-positive results. If both tests were reactive, a second oral fluid sample was collected for a confirmatory Western blot processed by an external laboratory. Participants also received emotional support and posttest counseling on sexual and injection risk behaviors, and the importance of ongoing HIV primary medical care, and were encouraged or assisted in scheduling appointments.

Each counselor provided intervention in each of 3 arms. With participant consent, counselor interactions were audiotaped in all 3 intervention arms, and 15% were randomly reviewed by trained raters during the trial to ensure fidelity to the intervention in each study arm. Raters assessed 2 to 10 required activities, depending on the study arm, using a 4-point scale: 0 = not at all; 1 = somewhat; 2 = mostly; 3 = completely. Audiotapes whose median fell between 1.5 and 2.5 were categorized as good and those higher than 2.5 as excellent. Raters provided regular feedback to counselors.

All deaths and all adverse events considered related to the intervention by the participant or the investigators were reported. Safety was monitored by the medical monitor at the clinical coordinating center of the CTN and a National Institute on Drug Abuse–appointed data and safety monitoring board.

We defined 2 a priori primary outcomes (<http://www.clinicaltrials.gov>, NCT01154296). We measured the first, self-reported receipt of HIV test result, which was binary (yes or no), during the 1-month assessment visit. We assessed the second, self-reported number of unprotected anal and vaginal intercourse episodes with either primary or nonprimary partners, during the 6-month follow-up visit.

We also collected race/ethnicity, gender, and age, and measured the following in the 6 months before baseline: injection drug use status, opioid use, stimulant use, the severity of substance use, and baseline sexual risk over the previous 6 months. We assessed

sharing of needles and injection drug use paraphernalia for the 6 months before baseline and the 6 months between randomization and follow-up.

Statistical Analysis

We designed the sample size for CTN 0032 to provide 80% power to detect a 10% absolute difference for receipt of HIV test results, assuming a 10% event rate for the off-site testing group, 20% event rate for the on-site group with information only, and 30% event rate for the on-site group with counseling, percentages based on published estimates.¹⁷ For number of episodes of unprotected intercourse, a standardized difference of 0.26^{18,19} between the on-site testing groups provided 80% power. The power computations considered 2-sided tests with type I error of .025 for the 2 coprimary outcomes. Secondary outcomes are reported using type I error of .05.

All treatment comparisons were on an intent-to-treat basis. We used score tests to assess treatment group differences by fitting generalized estimating equations (GEEs) with site as a cluster variable and adjustment for race and gender strata. The receipt of HIV test results outcome utilized a logit link function with a binomial error distribution. Number of risky sexual behaviors outcome utilized a log link function with a negative binomial error distribution. In the event that the 2-*df* test of difference across the 3 arms was statistically significant at the .025 level, we planned 2 orthogonal 1-*df* contrasts because these contrasts directly matched the 2 coprimary hypotheses. The first compared the off-site referral group to the 2 on-site testing groups combined. The second compared the 2 on-site testing groups. We present Mantel-Haenszel risk ratios (aRR), adjusted for race/ethnicity, gender, and site strata for the receipt of HIV test results. We present the incidence rate

TABLE 1—Demographic and Baseline Characteristics by Study Group, Among US Adults in Drug Treatment: HIV Rapid Testing and Counseling Study, 2009

	Off-Site Referral (n = 429), No./Total No. (%) or Median (Q1-Q3)	On-Site HIV Test With Counseling (n = 433), No./Total No. (%) or Median (Q1-Q3)	On-Site HIV Test With Information Only (n = 419), No./Total No. (%) or Median (Q1-Q3)
Race/ethnicity ^a			
Black or African American	89 (20.7)	88 (20.3)	86 (20.5)
White	278 (64.8)	277 (64.0)	271 (64.7)
American Indian/Alaska Native	9 (2.1)	13 (3.0)	11 (2.6)
Mixed race	34 (7.9)	34 (7.9)	30 (7.2)
Other	19 (4.4)	21 (4.8)	21 (5.0)
Hispanic	51 (11.9)	49 (11.3)	47 (11.2)
Female	173 (40.3)	170 (39.3)	161 (38.4)
Age, y	41 (32.0–48.0)	40 (29.0–48.0)	39 (29.0–48.0)
Injected drugs in lifetime	209 (48.7)	207 (47.8)	206 (49.2)
Used opiates in past 6 mo	142 (33.1)	167 (38.6)	165 (39.4)
Used stimulants in past 6 mo	186 (43.4)	191 (44.1)	181 (43.2)
Drug Abuse Screening Test-10 > 6	223 (52.0)	246 (56.8)	239 (57.0)
Ever tested for HIV	307 (71.6)	299 (69.1)	290 (69.2)
Received an HIV-negative result ^b	248 (57.8)	230 (53.1)	221 (52.7)
Years since most recent HIV test	3.7 (1.6–8.6)	4.1 (2.0–9.1)	3.1 (1.7–9.1)
Number of times tested for HIV	2 (1.0–3.0)	2 (1.0–3.0)	2 (1.0–3.0)
Reported no unprotected intercourse ^a	171/405 (42.2)	154/412 (37.4)	148/388 (38.1)
Episodes of unprotected intercourse	3 (0.0–25.0)	6 (0.0–35.0)	5 (0.0–32.5)

Note. Q1 and Q3 are the first and third quartile cutoff, respectively. The difference between those testing and those receiving a negative result is predominately attributable to taking the test but not receiving a result (only 3 participants received an indeterminate result).

^aSample sizes differed because of missing data.

^bSelf-reported result of most recent test taken.

ratios (IRR) based on the GEE model for unprotected intercourse, adjusted for race and gender strata and site as a cluster variable. To examine potential variability in the effectiveness of treatment by site of recruitment, a secondary analysis utilized site as a main effect, as opposed to a cluster variable, and added the site-by-treatment interaction as a covariate. Because this model did not utilize a clustering variable, we utilized the likelihood ratio test to assess treatment differences among the sites.

Secondary analyses examined the effect of the 3 interventions on needle sharing, which was measured as the sharing, either taking or receiving, of any needle or paraphernalia. We used a repeated measures GEE analysis utilizing a logit link function with a binomial error distribution to model needle sharing between baseline and 6 months in the full sample, utilizing patient as the cluster variable. We calculated several contrasts based on this model, including the overall difference in the change in sharing across treatment, the difference in sharing at 6 months across treatment arms, the difference in change between the 2 on-site arms combined and the referral arm, and the difference between the on-site testing with counseling arm and the on-site testing with information-only arm. We estimated a second model to test the difference in change in sharing between the 2 on-site arms combined and the referral arm.

RESULTS

Study staff had 4417 screening contacts with potential participants in the course of recruitment. This is an upper bound on the number of people approached because no personally identifiable information was collected before consent, preventing filtering duplicate individuals. The CONSORT diagram (Figure 1) summarizes study operations for the 2473 people consenting to be screened. Of the 2473 people screened, 1281 were randomized and 1192 (48.2%) were excluded. Of those excluded, 1160 (46.9%) were ineligible and 32 (1.3%) eligible people were not randomized. Participants ineligible for more than 1 reason are included in the first reason they reported that appears in the flow diagram to provide concise, mutually exclusive counts.

Demographic characteristics and baseline values of the outcome and control variables were comparable across the 3 randomized arms (Table 1). All participants received the intervention to which they were randomized with the exception of 6 participants randomized to counseling, who received no intervention for the reasons noted in Figure 1. Ten participants were lost to follow-up at 1 month (99.2% retention rate) and an additional 71 were lost to follow-up at 6 months (93.7% retention rate). The distribution of lost-to-follow-up and missing data did not differ by arm. Table 2 shows the demographic characteristics of the randomized sample and the demographics of the sites' caseloads during the period of recruitment.

Of the 198 audiotapes reviewed for fidelity to the intervention arms, 188 (94.9%) were rated excellent and the remaining 10 (5.1%), good. Interrater agreement was 97.1% on the 35 multiply rated audiotapes.

HIV Testing

There was a significant difference in testing and receipt of results across the 3 treatment groups ($P = .003$; 18.4% off-site versus 79.7% on-site with risk-reduction counseling versus 84.8% on-site with information only). There

was not a significant site-by-treatment interaction across the 3 treatment groups ($P = .19$). Participants randomized to on-site rapid testing were significantly more likely to complete and receive the results of an HIV test compared with participants randomized to the off-site referral arm ($P < .001$; aRR = 4.52; 97.5% confidence interval [CI] = 3.57, 5.72). Although fewer people in the risk-reduction counseling arm than the information arm received HIV testing, the difference was not statistically significant to the a priori level of $P \leq .025$ (79.7% vs 84.8%; $P = .043$). Three participants received reactive HIV test results, 2 in the on-site test with risk-reduction counseling arm and 1 in the on-site test with information-only arm. These reactive tests were confirmed by Western blot.

Unprotected Intercourse

Means and medians of unprotected intercourse at the 6-month follow-up are presented in Table 3. There was no significant difference among the 3 treatment groups (overall $P = .66$) nor was there a significant site-by-treatment interaction among the 3 groups ($P = .98$). The difference in rates of unprotected sexual intercourse were

TABLE 2—Characteristics of Randomized Trial Participants and Community Treatment Program Population Among US Adults in Drug Treatment: HIV Rapid Testing and Counseling Study, 2009

Characteristics	Randomized (n = 1281), No. (%)	Community Treatment Program ^a (n = 6662), No./Total No. (%)
Female	504 (39.3)	2402/6659 (36.1)
Age range, y		
18–29	309 (24.1)	1916/6443 (29.7)
30–39	313 (24.4)	1576/6443 (24.5)
40–49	414 (32.3)	1698/6443 (26.4)
50–59	212 (16.5)	1044/6443 (16.2)
≥ 60	33 (2.6)	209/6443 (3.2)
Race/ethnicity ^b		
White	759 (59.3)	4374/6448 (67.8)
Black	285 (22.2)	1585/6448 (24.6)
Hispanic	147 (11.5)	372/6448 (5.8)
Other	90 (7.0)	117/6448 (1.8)

^aData represent information provided by the sites for participants accessing services from the date on which sites began actively recruiting to date of last randomization.

^bMost sites (n = 11) reported both race and ethnicity. One site did not have information on ethnicity and its Hispanic population is included in White, Black, or other categories.

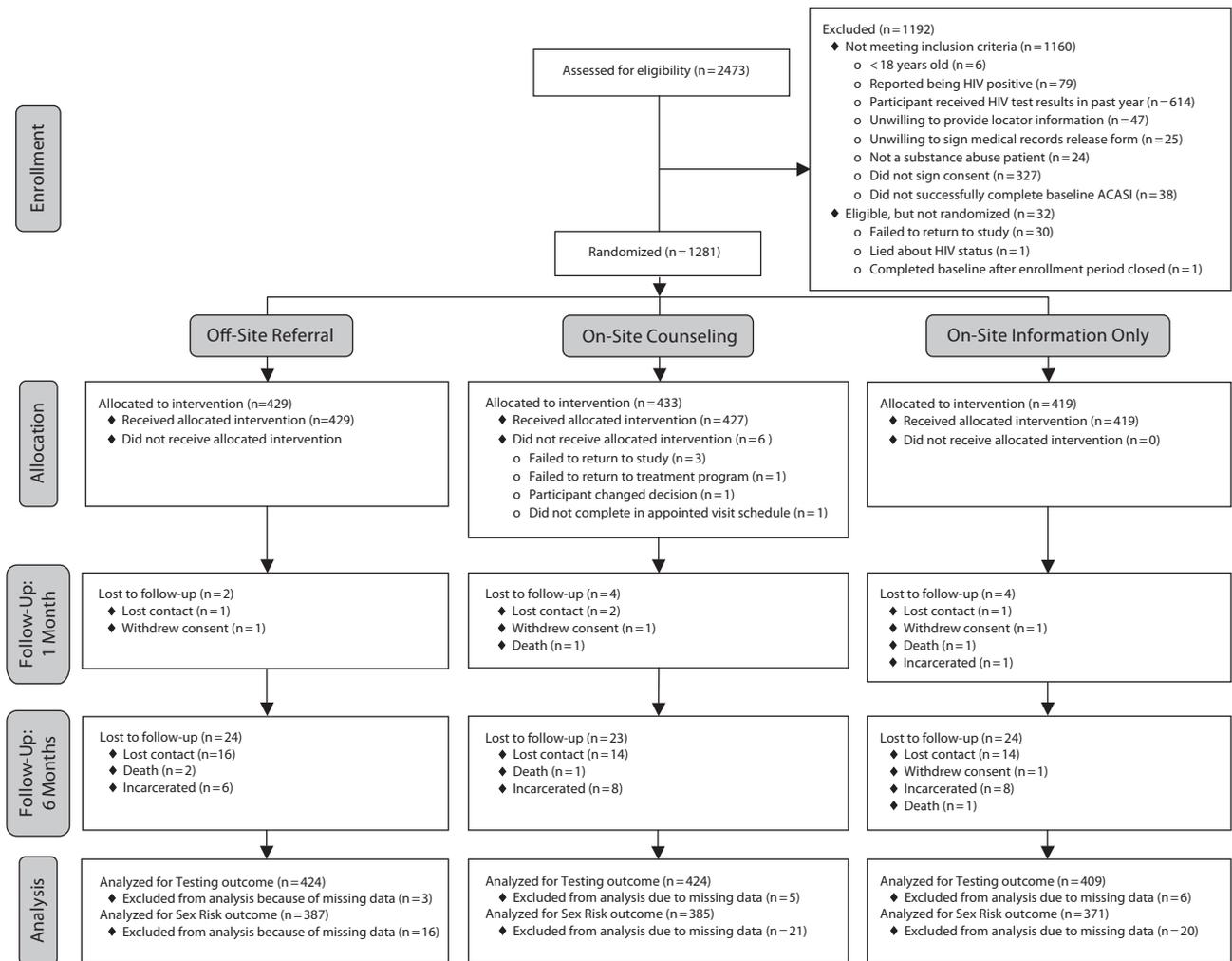


FIGURE 1—CONSORT flow diagram of participants in HIV Rapid Testing and Counseling Study, 2009.

neither different between the on-site with counseling arm and the off-site referral arm (IRR = 1.04; 97.5% CI = 0.94, 1.16) nor between the combined on-site testing arms and the off-site referral arm (IRR = 1.03; 97.5% CI = 0.73, 1.45) after we adjusted for race/ethnicity, gender, and site as a cluster variable.

In a series of planned posthoc analyses we examined the effect of including race/ethnicity, gender, age, and the following measured in the 6 months before baseline: injection drug use status, opioid use, stimulant use, the severity of substance use, and baseline sexual risk over the previous 6 months in the GEE model for unprotected sexual intercourse. Adjusting for these variables did not alter the conclusions from the primary analysis.

Secondary Analyses

There was a significant time-by-treatment interaction in the frequency of needle sharing ($P = .014$) indicating that there was differential change in needle sharing from baseline to the 6-month follow-up across the 3 treatment arms. The level or rate of needle sharing at 6 months also differed across arms ($P = .048$). The on-site arms together were not different from the off-site referral arm ($P = .089$).

There was a difference in change in needle sharing between the counseling arm and the information-only arm ($P = .044$). The on-site testing with counseling group had the most individuals discontinue needle sharing (32 of 34; 94.1%) and the fewest to initiate needle sharing (1 of 368; 0.3%). The off-site referral group had the fewest to discontinue needle

sharing (17 of 25; 68.0%) and the on-site with information-only group had the most initiating needle sharing (6 of 358; 1.7%). The frequency for each group is presented in Table 3.

Because many participants reported no baseline sexual risk, we conducted a subanalysis of the unprotected intercourse outcome only for participants having at least 1 episode of unprotected intercourse at baseline. The mean and median levels of sexual risk for this subgroup are presented in Table 3. We also examined change in sexual risk levels in the full sample. In neither analysis were any treatment group comparisons statistically significant.

There were no adverse events related to the testing procedures. Anticipated or targeted adverse events were balanced across the 3 arms

TABLE 3—Number, Means, and Medians of Outcomes by Study Group Among US Adults in Drug Treatment: HIV Rapid Testing and Counseling Study, 2009

	Off-Site Referral (n = 429)	On-Site HIV Test With Counseling (n = 433)	On-Site HIV Test With Information Only (n = 419)
Primary outcomes			
Self-report receipt HIV test results ^a	78/424 (18.4)	338/424 (79.7)	347/409 (84.8)
Unprotected intercourse ^b			
No.	387	385	371
Mean (SD)	20.5 (49.8)	21.3 (47.6)	21.3 (44.8)
Median (Q1-Q3)	1 (0-18)	1 (0-22)	1 (0-20)
90th percentile, maximum	60, 600	65, 500	76, 301
Secondary outcomes			
Injected drugs in 6 mo prebaseline, no./total no. (%)	87/429 (20.3)	92/433 (21.2)	85/419 (20.3)
Injected drugs in 6 mo postbaseline, no./total no. (%)	40/403 (9.9)	39/403 (9.7)	53/386 (13.7)
Shared needles in 6 mo prebaseline, no./total no. (%)	26/429 (6.1)	36/433 (8.3)	32/419 (7.6)
Shared needles in 6 mo postbaseline, no./total no. (%)	10/403 (2.5)	3/402 (0.8)	9/385 (2.3)
Change in needle sharing from baseline to 6 mo, no./total no. (%)			
Discontinued sharing	17/25 (68.0)	32/34 (94.1)	24/27 (88.9)
Initiated sharing	2/376 (0.5)	1/368 (0.3)	6/358 (1.7)
Subsample with sexual risk at baseline			
Unprotected intercourse ^b			
No.	215	226	214
Mean (SD)	32.5 (60.7)	29.6 (53.4)	29.8 (52.0)
Median (Q1-Q3)	10 (0-45)	10 (0-40)	7.5 (0-30)
90th percentile, maximum	90, 600	99, 500	100, 301

Note. Q1 and Q3 are the first and third quartile cutoff, respectively.

^aMeasured at 1 month postrandomization.

^bMeasured at 6 months postrandomization.

(referral: 2; counseling: 2; and on-site only: 3). The only serious adverse events were 6 deaths, 2 in each of the 3 arms, and none were study-related.

DISCUSSION

Our results have broad clinical and public health ramifications for routine HIV testing. Offering HIV rapid testing on site in drug treatment centers substantially increased receipt of HIV test results. Voluntary counseling has been a mainstay of HIV prevention,^{20,21} but our data show no beneficial effect of brief risk-reduction counseling on reducing unprotected intercourse. And, although not statistically significant by the prespecified level of significance, fewer people in the counseling arm compared with the information arm were tested and learned their results. Because we wanted our sample to be as representative as possible of patients in community-based drug treatment programs, we did not require recent

unprotected intercourse as an enrollment criterion, and 41% of the study population reported they were either not sexually active (33%) or had only condom-protected sexual intercourse (8%) at baseline. However, there was still no effect of counseling on reduction of sexual risk behaviors among the subset of participants who reported unprotected intercourse at baseline.

In secondary analyses, we did find more individuals newly refraining from intravenous drug use risk and fewer individuals initiating intravenous drug use risk in the risk-reduction counseling arm than the on-site HIV testing with information arm. Although needle risk education and counseling is a common component of drug treatment, this intervention showed that gains may be made from a brief person-centered approach to risk-reduction counseling. Because the number of needle-sharing individuals was small and this was a secondary outcome, the implications of this reduction of risk need to be examined further, perhaps through replication

in venues with a high proportion of IDUs, such as syringe exchange programs and drug treatment programs focusing on opioid treatment.

The majority of drug treatment programs in the United States do not offer on-site HIV testing.^{10-12,22} Approximately one third of our randomized participants had never been tested for HIV and only about one quarter of participants screened had received the results of an HIV test performed in the past year. Three new cases of HIV were detected, a prevalence of 0.4%. Previous studies concluded that routine HIV screening on a 1-time basis in a population with a prevalence of undiagnosed HIV infection as low as 0.2% remains cost-effective; screening every 5 years is similarly cost-effective in a population with a prevalence as low as 0.45% assuming a modest reduction in HIV transmission by those newly identified as HIV-infected.²³

The testing rates within the on-site arms of this study are considerably higher than the

rates found in Spielberg et al.,¹⁷ but that study was conducted more than 10 years ago (1999–2000) in needle exchange programs and in bath houses frequented by men having sexual intercourse with men. Difference in venue and era may have contributed to the lower rate of testing; similar rates to those observed in the current study were found in a more recent study of HIV testing acceptance conducted at the Veterans Administration facilities.²⁴

Although our study had excellent retention rates and high counseling fidelity ratings, it does have limitations. Results may not be generalizable to other populations or other settings, including those with higher HIV prevalence such as STD clinics. It is possible that the baseline survey increased participants' awareness of their risk behaviors, so the reported reductions in risk behaviors may not generalize to participants who are not assessed. However, such an effect would operate in each intervention arm. We did not assess the use of non-condom-based strategies to reduce risk (such as monogamy or serosorting). Finally, the participating community drug treatment sites are members of the CTN and have research experience; they are not necessarily representative of all community drug treatment providers.

This study demonstrated the value of on-site rapid HIV testing in drug treatment centers and found no additional benefit from HIV risk-reduction counseling on sexual risk behaviors. On-site rapid HIV testing increased testing rates and receipt of results and identified several HIV-infected persons, but providing high-quality, brief counseling did not have an effect on sexual risk behaviors of persons who tested negative among high-risk drug users. There is evidence that risk reduction counseling did reduce intravenous drug use–related risk taking, though the number of participants reporting this risk was quite small; a replication on a more targeted sample may be informative. Our results support the implementation of routine rapid HIV testing with information only among patients without recent HIV testing in drug treatment centers. ■

About the Authors

Lisa R. Metsch, Daniel J. Feaster, Lauren Gooden, and José Szapocznik are with University of Miami Miller School of Medicine, Miami, FL. Tim Matheson, Moupali Das, and Grant N. Colfax are with the San Francisco Department of

Public Health, San Francisco, CA. Raul N. Mandler is with the National Institute on Drug Abuse, Bethesda, MD. Louise Haynes is with the Medical University of South Carolina, Charleston, SC. Susan Tross is with Columbia University and New York State Psychiatric Institute, New York, NY. Tiffany Kyle is with the Center for Drug-Free Living Inc, Orlando, FL. Dianne Gallup is with the Duke Clinical Research Institute, Durham, NC. Andrzej S. Kosinski is with the Duke University Medical Center and Duke Clinical Research Institute, Durham, NC. Antoine Douaihy is with the University of Pittsburgh School of Medicine and Western Psychiatric Institute and Clinic, Pittsburgh, PA. Bruce R. Schackman is with Weill Cornell Medical College, New York, NY. Robert Lindblad is with the EMMES Corporation Inc, Rockville, MD. Sarah Erickson is with the University of New Mexico, Albuquerque, NM. P. Todd Korthuis is with the Oregon Health Science University, Portland, OR. Steve Martino is with Yale University, New Haven, CT. James L. Sorensen is with the University of California at San Francisco, San Francisco, CA. Rochelle Walensky is with Massachusetts General and Brigham and Women's Hospitals and Harvard Medical School, Boston, MA. Bernard Branson is with the Centers for Disease Control and Prevention, Atlanta, GA.

Correspondence should be sent to Lisa R. Metsch, PhD, Professor, Department of Epidemiology and Public Health, University of Miami Miller School of Medicine, 1120 NW 14th St, Suite 1019, Miami, FL 33136 (e-mail: Lmetsch@med.miami.edu). Reprints can be ordered at <http://www.ajph.org> by clicking the "Reprints" link.

This article was accepted September 4, 2011.

Contributors

L. R. Metsch was the lead investigator for the study, co-originated the study, oversaw the study's implementation, and wrote the initial draft of this article. She confirms that she had full access to all the data; participated in the design, execution, and analysis of the article; and had final responsibility for the decision to submit for publication. G. N. Colfax was the co-lead investigator for the study, co-originated the study, oversaw the clinical aspects of the study's implementation, and contributed to the writing and editing of the article. D. Gallup and A. S. Kosinski were the primary statisticians and provided statistical expertise, performed the analyses, and contributed to interpretation and editing of the article. D. J. Feaster was a co-investigator and contributed statistical expertise as well as contributed to interpretation, and writing and editing of the article. L. Gooden was the national project director for the study, oversaw study implementation, and contributed to the methods section of the article as well as to editing. T. Matheson was the national intervention director for the study, oversaw intervention implementation, and contributed to the methods section of the article. All other authors were involved in protocol development and contributed to writing and editing of the article. All authors have seen and approved the final version.

Acknowledgments

Funding for this study and analysis was provided by the National Drug Abuse Treatment Clinical Trials Network under the following cooperative agreements, awards, and contracts: U10DA013720, U10DA13720-09S, U10DA020036, U10DA15815, U10DA13034, U10DA013038, U10DA013732, U10DA13036, U10DA13727, U10DA015833, HHSN271200522081C, and HHSN271200522071C.

We acknowledge the site principal investigators: David Avila, Michael DeBernardi, Lillian Donnard, Antoine

Douaihy, Louise Haynes, Ray Muszynski, Patricia E. Penn, Ned Snead, Kevin Stewart, Robert C. Werstein, and Katharina Wiest. Site principal investigators' contributions to the work reported in this article included directing all aspects of the proposed study at their site(s), having overall responsibility for achieving the specific aims of the study, maintaining the proposed study schedule and budget, supervising the project staff, and ensuring quality control over all aspects of this study. We also acknowledge the following site staff: Walitta Abdullah, Elizabeth Alonso, Anika Alvanzo, Anna Amberg, Holly Angel, Rebekka M. Arias, Natasha Arocho, Carolyn Baron-Myak, Sarah Battle, Melissa Beddingfield, Dan Blazer, Stacy Botex, Sarah Bowles, Audrey Brooks, Elizabeth Buttrey, Betty Caldwell, Lynn Calvin, Maria Campanella, Sarah Carney, Angela Casey-Willingham, Jack Chally, Roberta Chavez, Nicholas Cohen, Zoe Cummings, Elisa Cupelli, Dennis Daley, Meredith Davis, Kay Debski, Andrea Dedier, Ashley Dibble, Bruce Dillard, Kimberly Drosdick, Monica Eiden, Matthew Elmore, Sarah Essex, Laura Feldberg, Elizabeth Ferris, John Gary, Daniel Gerwien, Marisa Gholson, Melissa Gordon, Lauren Griebel, Laurel Hall, Stephanie Hart, Joshua Heffner, Beverly Holmes, Christine Horne, Alice Huang, Aleks Jankowska, Beth Jeffries, Kristen Jehl, Eve Jelstrom, Andrew Johnson, Jacob Johnson, Shanna Johnson, Emily Kinsling-Law, Amy Knapp, Eric Kohler, Beatrice Koon, Emily Kraus, Lynn Kunkel, Robert Kushner, Diane Lape, Theresa Latham, Larry Lee, Carol Luna-Anderson, Sue McDavid, Michael McKinney, Cindy Merly, Melody Mickens, Jenni Mulholland, Roger Owen, Barbara Paschke, Wayne Penachi, Sharon Pickrel, Kimberly Pressley, John Reynolds, Gillian Rossman, Laretta Safford, Christine Sanchez, Lynn Sanchez, Dorothy Sandstrom, Carmel Scharenbroich, Robert Schwatz, Nicolangelo Scibelli, Michael Shopshire, Jessica Sidz, Eugene Somoza, Maxine Stitzer, Joseph Sullivan, Krishna Suwal, Danielle Terrell, Lauren Thomas, Rena Treacher, Dominic Usher, Angel Valencia, Tammy Van Linter, Rosa Verdeja, Joanne Weidemann, Brandi Welles, Lindsay Worth, and Pamela Yus. Site staff contributions to the work reported in this article included conducting recruitment and enrollment activities, performing assessment interviews, conducting study interventions, performing quality assurance monitoring activities, performing data entry, and completing other day-to-day study activities that led to the collection of the study data. We also would like to acknowledge Jacques Normand and Lynda Erinoff of the National Institute on Drug Abuse, Office of the Director, AIDS Research Program, for their review of the article and contributions to protocol development.

Human Participant Protection

This study was approved by the Western Institutional Review Board. In addition, the following institutional review boards provided local approval or oversight for their respective study sites: Oregon Health and Science University, University of Cincinnati, Johns Hopkins University School of Medicine, University of New Mexico Health Sciences Center, and the University of Pittsburgh.

References

1. Prejean J, Song R, Hernandez A, et al; HIV Incidence Surveillance Group. Estimated HIV incidence in the United States, 2006–2009. *PLoS One*. 2011;6(8):e17502.
2. Campsmith ML, Rhodes PH, Hall HI, Green TA. Undiagnosed HIV prevalence among adults and adolescents in the United States at the end of 2006. *J Acquir Immune Defic Syndr*. 2010;53(5):619–624.

3. *National HIV/AIDS Strategy for the United States*. Washington, DC: The White House Office of National AIDS Policy; 2010.
4. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep*. 2006;55(RR-14):1-17; quiz CE1-4.
5. Qaseem A, Snow V, Shekelle P, Hopkins R Jr, Owens DK, for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. Screening for HIV in health care settings: a guidance statement from the American College of Physicians and HIV Medicine Association. *Ann Intern Med*. 2009;150:125-131.
6. American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 411. Routine human immunodeficiency virus screening. *Obstet Gynecol*. 2008;112(2 Pt 1):401-403.
7. Centers for Disease Control and Prevention. Persons tested for HIV—United States, 2006. *MMWR Morb Mortal Wkly Rep*. 2008;57(31):845-849.
8. Lehman JS, Allen DM, Green TA, Onorato IM. HIV infection among non-injecting drug users entering drug treatment, United States, 1989-1992. Field Services Branch. *AIDS*. 1994;8(10):1465-1469.
9. Prevots DR, Allen DM, Lehman JS, Green TA, Petersen LR, Gwinn M. Trends in human immunodeficiency virus seroprevalence among injection drug users entering drug treatment centers, United States, 1988-1993. *Am J Epidemiol*. 1996;143(7):733-742.
10. Pollack HA, D'Aunno T. HIV testing and counseling in the nation's outpatient substance abuse treatment system, 1995-2005. *J Subst Abuse Treat*. 2010;38(4):307-316.
11. *The N-SSATS Report: Infectious Disease Screening*. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2010.
12. Brown LS Jr, Kritz SA, Goldsmith RJ, et al. Health services for HIV/AIDS, hepatitis C virus, and sexually transmitted infections in substance abuse treatment programs. *Public Health Rep*. 2007;122(4):441-451.
13. Kamb ML, Fishbein M, Douglas JM Jr, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. Project RESPECT Study Group. *JAMA*. 1998;280(13):1161-1167.
14. Semaan S, Neumann MS, Hutchins K, D'Anna LH, Kamb ML. Brief counseling for reducing sexual risk and bacterial STIs among drug users—results from project RESPECT. Project RESPECT Study Group. *Drug Alcohol Depend*. 2010;106(1):7-15.
15. Yudko E, Lozhkina O, Fouts A. A comprehensive review of the psychometric properties of the Drug Abuse Screening Test. *J Subst Abuse Treat*. 2007;32(2):189-198.
16. Metcalf CA, Douglas JM Jr, Malotte CK, et al. Relative efficacy of prevention counseling with rapid and standard HIV testing: a randomized, controlled trial (RESPECT-2). *Sex Transm Dis*. 2005;32(2):130-138.
17. Spielberg F, Branson BM, Goldbaum GM, et al. Choosing HIV counseling and testing strategies for outreach settings: a randomized trial. *J Acquir Immune Defic Syndr*. 2005;38(3):348-355.
18. Tross S, Campbell AN, Cohen LR, et al. Effectiveness of HIV/STD sexual risk reduction groups for women in substance abuse treatment programs: results of NIDA Clinical Trials Network Trial. *J Acquir Immune Defic Syndr*. 2008;48(5):581-589.
19. Calsyn DA, Hatch-Maillette M, Tross S, et al. Motivational and skills training HIV/sexually transmitted infection sexual risk reduction groups for men. *J Subst Abuse Treat*. 2009;37(2):138-150.
20. Centers for Disease Control and Prevention. Public health service guidelines for counseling and antibody testing to prevent HIV infection and AIDS. *MMWR Morb Mortal Wkly Rep*. 1987;36:509-515.
21. Holtgrave D, McGuire J. Impact of counseling in voluntary counseling and testing programs for persons at risk for or living with HIV infection. *Clin Infect Dis*. 2007;45(Suppl 4):S240-S243.
22. Brown LS Jr, Kritz SA, Goldsmith RJ, et al. Characteristics of substance abuse treatment programs providing services for HIV/AIDS, hepatitis C virus infection, and sexually transmitted infections: the National Drug Abuse Treatment Clinical Trials Network. *J Subst Abuse Treat*. 2006;30(4):315-321.
23. Paltiel AD, Walensky RP, Schackman BR, Seage GR III, Weinstein MC, Freedberg KA. Expanded HIV screening in the United States: effect on clinical outcomes, HIV transmissions, and costs. *Ann Intern Med*. 2006;145(11):797-806.
24. Anaya HD, Hoang T, Golden JF, et al. Improving HIV screening and receipt of results by nurse-initiated streamlined counseling and rapid testing. *J Gen Intern Med*. 2008;23(6):800-807.