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Bundling Rapid HIV and HCV Testing to Increase Receipt of Test Results: A Randomized Trial

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Abstract

Background: The overlapping HIV and hepatitis C virus (HCV) epidemics disproportionately affect people with substance use disorders. However, many people who use substances remain unaware of their infection(s).

Objective: Examine the efficacy of an on-site bundled rapid HIV and HCV testing strategy in increasing receipt of both HIV and HCV test results.

Research Design: Two-armed randomized controlled trial in substance use disorder treatment programs (SUDTP) in New York City. Participants in the treatment arm were offered bundled rapid HIV and HCV tests with immediate results on-site. Participants in the control arm were offered the standard of care, i.e., referrals to on-site or off-site laboratory-based HIV and HCV testing with delayed results.

Participants: A total of 162 clients with unknown or negative HIV and HCV status.

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Conflicts of interest: The authors declare that they have no conflicts of interest.

Measures: Primary outcome was the percentage of participants with self-reported receipt of HIV and HCV test results at 1-month post-randomization.

Results: Over half of participants were Hispanic (51.2%), with 25.3% being non-Hispanic Black and 17.9% non-Hispanic White. Two thirds were male, and 54.9% reported injection as method of drug use. One hundred and thirty-four participants (82.7%) completed the 1-month assessment. Participants in the treatment arm were more likely to report having received both test results than those in the control arm (69% vs. 19%, $p < 0.001$). Seven participants in the treatment arm received a preliminary new HCV diagnosis, vs. 1 in the control arm ($p = 0.029$).

Conclusions: Offering bundled rapid HIV and HCV testing with immediate results on-site in SUDTPs may increase awareness of HIV and HCV infection among people with substance use disorders.

Keywords

HIV; HCV; Bundled testing; Substance use; Rapid testing

INTRODUCTION

The U.S. is in the midst of a major epidemic of opioid misuse.^{1,2} People who use opioids and other illicit substances are disproportionately affected by the overlapping HIV and hepatitis C virus (HCV) epidemics. In fact, substance misuse, HCV, and HIV may be best viewed as a syndemic occurring in vulnerable contexts.³ In the U.S., injection drug use accounts for 6% of new HIV infections, 26% of acute HCV infections, and 52% of chronic HCV infections.^{4,5} Other methods of substance use, such as sniffing, smoking, snorting, and ingesting also contribute to this high disease burden.^{6,7} The Centers for Disease Control and Prevention therefore recommends routine HIV and HCV testing for people with a history of substance use.⁸

However, many people with substance use disorders remain unaware of their infection with HIV and/or HCV. In a survey across 20 U.S. cities, close to half of HIV-positive persons who inject drugs did not know their status.⁹ Approximately 75% of HCV-infected persons with a substance use disorder were unaware of their infection.^{10,11} A main reason for this low rate of awareness is that substance users are less likely to seek care in hospitals and other health facilities where both HIV and HCV testing are readily available.¹²

Substance use disorder treatment programs (SUDTPs) are one setting where people with substance use disorders can be engaged for both HIV and HCV testing.¹³ In 2016, SUDTPs provided substance use disorder treatment such as methadone maintenance or behavioral therapy to an estimated 2.1 million adults.¹⁴ Yet, the availability of HIV and HCV testing remains limited in SUDTPs.¹⁵ Fewer than half of SUDTPs in the U.S. offer on-site HIV testing and the proportion of SUDTPs offering on-site HIV and/or HCV testing has declined over time.^{16–19} Instead, a growing proportion of SUDTPs refer their patients to outside facilities for HIV and/or HCV testing. This constitutes a missed opportunity for increasing awareness of HIV and/or HCV infection,²⁰ as few patients follow-up on off-site referrals for testing.^{19,21}

Patients might also make limited use of HIV/HCV testing services that some SUDTPs offer on-site, because they require additional waiting times and might not be operating at times when patients seek treatment for substance use disorders (e.g., early morning). Furthermore, the testing services available either on-site or off-site usually require venipuncture and laboratory testing. Such procedures only produce results after a few days (“delayed results” thereafter), and require patients to make an additional visit to obtain their results. A significant proportion of patients do not return to the testing facility for that purpose.²²

We investigate an on-site bundled rapid HIV and HCV testing strategy, i.e., an approach in which SUDTP clients are offered HIV and HCV testing in the same care encounter, using test kits that produce results in less than 20 minutes (“immediate results” thereafter). Rapid tests address several barriers to the limited uptake of HIV/HCV testing in SUDTPs. They use blood from a finger stick or oral fluid from a swab, and can thus be performed by health providers with limited training. In particular, they can potentially be implemented in a large number of SUDTPs that do not have a phlebotomist on staff, under a waiver of the requirements of the Clinical Laboratory Improvement Amendments.¹⁵ Rapid tests also do not require clients to return to the facility to retrieve their test results; and are highly accurate in detecting HIV and HCV.^{12,23,24}

Despite high levels of HIV-HCV co-infection, and increasing calls for integration of HIV and HCV services with substance use disorder treatment, efforts to introduce rapid testing to SUDTPs have emphasized HIV testing.^{8,25,26} This is so even though the rationale for offering rapid HCV testing to SUDTP patients has increased in recent years.²⁷ In the past, interferon-based HCV treatments had limited efficacy, required injections, and often had serious side effects.¹² Since 2014, direct acting antivirals providing shorter and highly effective HCV treatment have become available. These new regimens have large clinical benefits for patients, and might help interrupt the transmission of HCV within affected population groups.

In this paper, we report the results of a randomized controlled trial (RCT) to assess the efficacy of bundling rapid HIV and HCV testing in increasing receipt of both HIV and HCV test results among patients receiving substance use disorder treatment.

METHODS

Study Design, Setting, and Participants

The study was a 2-arm randomized controlled trial in which participants received either on-site bundled rapid HIV and HCV testing with immediate results (treatment arm) or referrals to on-site or off-site laboratory-based HIV and HCV testing services with delayed results, i.e., the standard of care routinely offered to SUDTP patients (control arm).²⁸ We recruited participants from two SUDTPs located in New York City, between April 2016 and July 2017. Both study sites offered methadone maintenance or behavioral therapy during group sessions as methods of substance use disorder treatment. Both study sites were also co-located with federally qualified health centers (FQHC) that provide primary healthcare services. SUDTPs clients were encouraged to seek primary care from these FQHCs, but could also be referred to other primary care facilities if they preferred. At both study sites,

FQHCs offered on-site laboratory-based HIV and HCV testing services with delayed results, but they did not offer rapid testing services.

Trained research assistants approached patients in waiting areas at the study sites, described the study, and invited them to be assessed for eligibility. Patients were eligible if they: (1) were at least 18 years old, (2) were able to communicate in English, (3) were seeking or currently receiving substance use disorder treatment services (except for alcohol use disorder only) at the participating SUDTPs, (4) self-reported being HIV and HCV negative, or reported not knowing their HIV and HCV status at the time of the interview, and (5) had not received results of an HIV or HCV test within the last 6 months. Potential participants were also asked if they were willing and able to provide locator information to enable follow-up. The Columbia University Institutional Review Board granted ethical approval prior to study implementation.

Randomization

After providing written informed consent, participants were randomized to either the treatment or control arms. To ensure balance of key covariates between study arms, randomization was stratified by gender (male vs. female), method of substance use disorder treatment (methadone maintenance vs. behavioral treatment only), primary care provider location (FQHC at study site vs. elsewhere), and method of drug use (injection vs. non-injection). To prevent large imbalances in sample size between study arms within each stratum, and to prevent manipulation of study assignments by study staff or participants, we used permuted blocks of randomized assignments.²⁹ Each block contained equal numbers of assignments to treatment and control groups. The size of the blocks varied from 4 to 10, and the order of the assignments to study groups was selected at random within each block. The randomization assignments were concealed in sequentially numbered, opaque, sealed envelopes with a signature across the sealing point. Research assistants, who were blind to the randomization schedule, informed participants of their assignment to the treatment or control arm at the time of randomization.

Interventions

Participants randomized to the treatment arm received an offer to participate in on-site bundled rapid HIV and HCV testing, with immediate results. Rapid testing was conducted using OraQuick Advance® rapid HIV-1/2 and OraQuick® HCV rapid antibody test kits. Both assays have high sensitivity and specificity (98.1% and 100%, respectively for HIV; and 98% and 100%, respectively for HCV).^{30,31} In the case of inconclusive or invalid HIV results, participants were tested using Clearview® COMPLETE rapid HIV 1/2 Assay. Test counselors certified in rapid HIV and HCV testing by New York State were trained to deliver the testing intervention.

In the treatment arm, participants who accepted the bundled offer received pre-test information about testing procedures, were tested, and asked to wait 20 minutes for test results. Those who chose to receive their test results were provided post-test counseling and support services, immediately after test results were obtained. Participants with reactive HIV and/or HCV antibody tests were actively linked to a health care provider for further

evaluation and confirmatory testing. In those cases, the test counselor called to make a follow-up appointment for the patient either at the study site (i.e., at the FQHC) or at another provider outside of the study site. Study supervisors monitored fidelity of study procedures, by reviewing audio-recorded sessions to ensure accuracy of presentation and conformity to the protocol.

In the control arm, the research assistants who recruited study participants and conducted the randomization also encouraged participants to seek testing for HIV and HCV. They provided them with a list of testing providers that offered HIV and/or HCV testing services. All listed providers used venipuncture, followed by whole blood laboratory-based HIV and HCV testing with delayed results. These lists included off-site providers located in the vicinity of the SUDTP, as well as testing services available on-site at the SUDTP (i.e., through the health center). In the control arm, linkage to care following positive HIV and/or HCV tests was accomplished by referral to a healthcare provider within the participating SUDTP or to other health facilities.

Study Assessments

Participants completed a baseline assessment prior to randomization and a follow-up assessment one month after randomization, using an audio computer-assisted self-interview (ACASI) program. They also had the option to have assessments administered by a research assistant, without ACASI. We collected socio-demographic information only at baseline, whereas we collected HIV and HCV testing histories, as well as information on drug use and sexual risk behaviors, at both baseline and 1-month follow-up. In the treatment arm, test counselors directly recorded in study logs whether participants received their HIV and/or HCV test results following rapid testing. Participants provided locator information to enable follow-up assessments. Participants were compensated \$20 and \$45 for completing the baseline and 1-month follow-up assessments, respectively.

Measures

Consistent with large-scale evaluations of rapid HIV testing,³² the pre-specified primary outcome was the proportion of participants who self-reported receipt of HIV and HCV test results at one-month post randomization. Self-reported data might however misrepresent the uptake of HIV and/or HCV testing, if participants do not accurately report their testing behaviors during the follow-up period. In exploratory analyses of the treatment arm, we thus also evaluated receipt of HIV and HCV test results as directly observed by the testing providers. Since participants in the control arm were referred to other providers for testing, this directly observed measure is not available for this arm. We also assess the proportion of participants who self-reported positive HIV or HCV test results at the 1-month follow-up (i.e., new diagnoses).

Pre-specified secondary outcomes were assessed one-month post-randomization and included self-reported sexual risk behaviors and drug use: (1) unprotected vaginal and/or anal sex with any sex partner; (2) use of any drugs; and (3) unsafe injection practices (i.e., sharing needles). Finally, secondary outcomes also included (4) an assessment of linkage to care, defined as the proportion patients who reported that they had initiated HIV and/or

HCV care at the time of follow-up, among those who also reported test results that were positive for HIV and/or HCV.

Sample Size

The study was designed to assess the effects of bundled rapid HIV/HCV testing on the receipt of HIV and HCV test results. Power calculations assumed a baseline proportion of SUDTP patients receiving their HIV/HCV test results of 40%. Prior studies found approximately 80% uptake of rapid HIV testing among SUDTP patients.³² Assuming a similar uptake for rapid HCV testing, and assuming conservatively that patients' decisions to engage in rapid HIV and HCV testing are independent, we hypothesized that the treatment would increase the receipt of HIV/HCV test results to 64% (i.e., 0.8 multiplied by 0.8). Based on a χ^2 test of the difference between proportions, with 80% power and $\alpha = 0.05$, we required 134 participants to detect such a difference in receipt of HIV and HCV test results between study arms. We also anticipated approximately 80% retention at the one-month follow-up. We had initially planned a larger sample size, in order to measure the effects of bundled rapid HIV/HCV testing separately for SUDTP patients receiving methadone maintenance, and for those receiving behavioral therapy. Due to slower than expected recruitment, we revised the protocol in March 2017, and aimed to measure these effects for all SUDTP patients combined as described above.

Statistical Analysis

We first compared baseline socio-demographic characteristics and behaviors of study participants, by study arm. Baseline testing behaviors included whether the participant had ever been tested for HIV and/or HCV prior to enrollment, when the last test took place for each disease, and whether the participant received his/her test results at the time. Variables describing drug use and sexual behaviors included whether the participant had engaged in unprotected intercourse in the month prior to the study. We also examined the distribution of stratification variables by study arm. We used an intent-to-treat protocol to examine primary and secondary outcomes, with participants analyzed according to their assigned study arm.

We calculated the distribution of each outcome by assigned arm, and we used chi-square tests of differences in proportions to assess differences between study arms. For participants in the treatment arm, we also calculated the distribution of directly observed HIV/HCV rapid testing outcomes. We explored the frequency of new HIV and HCV diagnoses in each arm. To do so, due to limited sample size, we used two-sided Fisher's exact tests. As recommended when the study outcome is not rare,^{33,34} we used Poisson regression models to calculate risk ratios associated with assignment to the treatment arm. Covariates in regression models included assigned study group, stratification variables, and covariates that were predictive of completion of the follow-up assessment.³⁵

We conducted these analyses for all study participants with complete follow-up data. Then, in sensitivity analysis, we repeated these analyses after participants lost to follow-up were attributed negative primary and secondary outcomes, i.e., they were counted as not having tested (primary outcome), and as having engaged in risk behaviors during the

follow-up period (secondary outcomes). All analyses were performed using Stata version 14 (StataCorp LP).

RESULTS

Among the 454 individuals screened for eligibility, 196 (43.2%) were eligible and 162 (81.6% of those eligible) were enrolled, completed baseline assessments, and were randomized (Figure 1). The main reasons for exclusion were being HCV positive ($n=112$), recent receipt of HIV test results ($n=54$), being HIV positive ($n=25$), and failure to complete study pre-randomization activities ($n=34$). Of the 162 who were randomized, 79 (49%) were allocated to the treatment arm and 83 (51%) to the control arm.

Baseline socio-demographic characteristics, sexual and drug use behaviors, and HIV and HCV testing histories were similar for participants randomized to the intervention and control arms, except for higher rates of unprotected intercourse in the past month in the treatment group (Table 1). Overall, 156 (96%) participants reported ever testing for HIV, and among those, 133 (85.3%) reported having received their most recent HIV test results. While 139 (84%) participants reported ever being tested for HCV, only 106 (76.3%) of those had received their most recent HCV test result.

In total, 134 participants completed the 1-month follow-up assessment (82.7% retention), 65 in the treatment arm and 69 in the control arm. The baseline socio-demographic characteristics, HIV and HCV testing histories, and risk behaviors of those who were retained and of those who were lost to follow-up were largely similar (Supplemental Digital Content 1). Participants who reported recent unprotected sexual intercourse at baseline were, however, less likely to complete the follow-up assessment than other participants.

At one-month post-randomization, participants in the treatment arm self-reported receipt of HIV and HCV test results at a higher rate than those in the control arm (69% vs. 19%, $p < 0.001$, Table 2). This difference remained after adjusting for stratification factors and predictors of retention (Adjusted Risk Ratio = 3.6, 95% CI = 2.2 to 6.1). Our directly observed measure of the proportion of participants in the treatment arm who received their test results was higher than our self-reported measure. In this arm, test counselors recorded that 57 (88%) patients had received their test results for HIV and HCV.

None of the study participants were diagnosed with HIV during the follow-up period, but eight participants reported being newly diagnosed with HCV. This was the case for seven participants in the treatment arm, and for one participant in the control arm. This difference in the yield of HCV testing was significant at the $p = 0.029$ level according to Fisher's two-sided exact test.

Secondary outcomes did not differ between the treatment and control arms at one-month post-randomization. Use of any illicit drug was reported by 38% of those in the treatment group, versus 51% in the control group. Very few participants reported sharing needles during the follow-up period (2% and 3% for treatment and control arms, respectively). Similarly, only 25% of participants in the treatment group and 20% of the control participants reported unprotected intercourse during that period. We obtained similar results

in sensitivity analyses (Table 3). Participants who self-reported that they had tested positive for HCV during the trial also self-reported that they were linked to care based on the study protocol.²⁸

DISCUSSION

Among patients attending SUDTPs in New York City, offering rapid bundled HIV and HCV testing on site resulted in higher rates of self-reported receipt of test results for both HIV and HCV. Specifically, participants randomized to receive bundled rapid testing were nearly 4 times more likely to receive both test results than participants randomized to receive the standard of care. In our study, such an increase in status awareness for both diseases resulted in an increase in new HCV diagnoses. This may contribute to higher engagement in prevention services, increases in initiation of timely treatment, and ultimately reductions in morbidity and mortality associated with one or both conditions.

To the best of our knowledge, our study is the first trial testing a strategy for offering rapid HIV and HCV testing with immediate results to patients in SUDTPs. Our findings are, however, consistent with previous studies on the integration of HIV and HCV testing in other settings. In California, the joint offer of laboratory-based testing services with delayed results for HIV and HCV resulted in an increase in HIV testing rates among persons who inject drugs, compared to offering HIV testing alone.²⁶ A study in emergency rooms reported no significant difference in HIV test acceptance for bundled rapid HCV/HIV testing compared with rapid testing for HIV-only.³⁶ The offer of HIV and HCV testing in community health centers also led to increases in testing rates, greater diagnosis of seropositivity, and increased linkage to care³⁷.

In our study, the additional time it took to perform a second rapid test and to provide post-test counseling for an additional condition did not deter patients from being tested, or from receiving their test results. Yet, implementation concerns, including staffing, space, and time constraints have been cited as barriers to the implementation of bundled rapid HIV/HCV testing in SUDTPs.³⁸ While our study examined bundled testing primarily from a patient perspective, further examination of implementation concerns from the perspectives of providers and program managers is needed to effectively evaluate and address these barriers.

There were no meaningful differences in secondary outcomes, i.e., the likelihood of engaging in sexual or drug-related risk behaviors between the treatment and control arms. There may be several explanations for this null finding. On the one hand, our sample size may have been too small to detect small differences in risk behaviors between the two groups. On the other hand, the duration of follow-up (one month) may also have been too short for behavioral effects of the intervention to unfold. Nonetheless, our findings are also consistent with prior studies that have indicated that testing and counseling for HIV had limited effects on risk behaviors.^{32,39,40}

The study has several limitations. First, participants were enrolled from two SUDTPs, and most had previously been tested for HIV or HCV, but had not been tested in the past 6 months. Our findings may therefore not be generalizable to other settings or populations,

especially to settings where prior HIV/HCV testing may be less widespread. They may also not extend to settings where substance use treatment uses methods other than methadone maintenance or behavioral therapy, e.g., buprenorphine. Second, nearly 17% of participants randomized were lost to follow-up. However, in analyses in which we either controlled for predictors of attrition, or imputed study outcomes, our assessment of the efficacy of bundled rapid HIV and HCV testing in increasing receipt of test results remained unchanged.

Third, because our primary outcome was self-reported, our evaluation of the effects of bundling rapid HIV/HCV tests may be affected by misreporting. We found that only 45 participants in the treatment arm self-reported receipt of test results, even though test counselors recorded in study logs that 57 participants in the treatment arm received their HIV/HCV test results. We could not measure directly whether participants in the control arm also under-reported testing to the same extent, so it is unclear how such misreporting of HIV/HCV testing might have affected our estimates of the efficacy of the bundled testing strategy. Furthermore, the control arm might also have been affected by over-reporting of the receipt of test results, e.g., because participants in that arm might have wanted to seem compliant with the recommendation for testing they received during the study. In this scenario, the effect of bundling rapid HIV and HCV testing on the receipt of test results might be even greater than indicated from self-reported data. In future studies, reviewing medical records of study participants to confirm testing may help address this issue and provide more robust estimates of the effects of bundled testing.^{41,42} Other study outcomes, including linkage to care, might also have been affected by errors in self-reported data. For example, to appear compliant with referrals, participants might have stated during the follow-up interview that they had initiated care, even though they had not yet done so.

Fourth, higher reported rates of unprotected intercourse among those in the treatment arm (table 1) might be associated with increased acceptance to test and receive results. However, controlling for this baseline characteristic in regression analysis did not modify our assessment of the efficacy of the bundling strategy. Fifth, our sample size was too small to enable detailed sub-group analyses of the effects of the bundled testing strategy. In planning future expansion of the rapid bundled testing strategy, it would be important to know if it also reaches specific socio-demographic groups (e.g., patients of different racial/ethnic groups) or individuals with various risk factors (e.g., injecting drug use) at the same rate, and whether it modifies behavioral outcomes, over a longer follow-up period. Lastly, our sample size was also too small, and our follow-up period too short, to investigate the effect of the bundled testing strategy on linkages to HIV and HCV care services among recently diagnosed patients. Future studies should therefore assess the effects of rapid bundled testing on the entire care and treatment cascades for HIV/HCV. They should also invest in strategies that will further recruitment and retention efforts, e.g., by partnering with community stakeholders working with the populations of interest. Such efforts will likely help achieve sample sizes required to broaden the scope of analyses.

Nonetheless, our study indicates the potential of bundled rapid HIV and HCV testing with immediate results to rapidly improve status awareness for both viruses among clients of SUDTPs. This is important because offering such a testing strategy in SUDTPs is also likely cost-effective. A prior simulation study, using a decision analytic model informed by

parameters similar to those we estimated in these study (e.g., acceptance of an offer to use rapid HIV/HCV tests), reported that offering on-site rapid HIV and HCV testing in SUDTPs exceeded commonly used cost-effectiveness benchmarks under a broad range of scenarios.⁴³ Data from our trial thus provide additional information to guide decision-making regarding the adoption and implementation of the bundled rapid testing strategy.

Further studies are now needed to develop multi-level strategies to promote and sustain the use of this testing approach in SUDTP facilities. This will require empirically examining organizational, provider and patient-level barriers to the adoption and effective implementation of the bundled testing strategy. It will also entail assessing the longer-term effects of the bundled testing strategy on linkages to care, and patient outcomes.

CONCLUSION

The availability of rapid bundled HIV and HCV testing for patients in SUDTPs, resulted in increased self-reported receipt of test results at one-month post randomization. Our findings suggest that this strategy may be an efficacious approach to increasing awareness of infection status for at-risk groups. It can help improve linkage to care and early initiation of treatment for both HIV and HCV among this highly-affected population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
CONSORT Flow Diagram of Participants in Bundled Rapid HIV and HCV Testing Study.

Table 1.**Baseline Characteristics of Participants by Study Group**

	On-site Bundle HIV/HCV Rapid Testing	Standard of Care
	(n = 79)	(n = 83)
No. (%) with data		
Sociodemographic		
Race/ethnicity		
Black or African American, non-Hispanic	19 (24)	22 (27)
White, non-Hispanic	19 (23)	11 (13)
Hispanic	40 (51)	43 (52)
Other	2 (3)	7 (8)
Sex		
Male	53 (67)	57 (69)
Female	26 (33)	26 (31)
Age, mean (SD)	44.5 (11)	48.7 (10)
Education		
<= High school	62 (78)	69 (83)
Some college or vocational school	10 (13)	8 (10)
College graduate	7 (9)	6 (7)
HIV and HCV Testing		
Ever tested for HIV		
No	2 (3)	4 (5)
Yes	77 (97)	79 (95)
Last HIV test ^a		
>= 12 months	42 (55)	47 (59)
<12 months	35 (45)	32 (41)
Received most recent HIV test result ^a		
No	13 (17)	10 (13)
Yes	64 (83)	69 (87)
Ever tested for HCV		
No	11 (14)	12 (14)
Yes	68 (86)	71 (86)
Last HCV test ^b		
>= 12 months	37 (54)	35 (49)
<12 months	31 (46)	36 (51)
Received most recent HCV test result ^b		
No	12 (18)	21 (30)
Yes	56 (82)	50 (70)
Drug Use and Sexual Risk Behaviors		
Used opioids in past month ^c		
No	37 (48)	39 (49)

	On-site Bundle HIV/HCV Rapid Testing (n = 79)	Standard of Care (n = 83)
Yes	40 (52)	41 (51)
Used stimulants in past month ^c		
No	57 (74)	58 (73)
Yes	20 (26)	22 (28)
Unprotected intercourse in past month ^{*d}		
No	47 (61)	61 (77)
Yes	30 (39)	18 (23)
Stratification factors		
Method of substance use treatment		
Methadone	68 (86)	71 (86)
Behavioral therapy	11 (14)	12 (14)
Location of primary care provider		
Study site (FQHC)	20 (25)	25 (30)
Non-study site	59 (75)	58 (70)
Method of drug use		
Injection	42 (53)	47 (57)
Non-injection	37 (47)	36 (43)

^aPercentage calculated based on the number of participants who have ever tested for HIV.

^bPercentage calculated based on the number of participants who have ever tested for HCV.

^cPercentage calculated based on 157 participants with baseline behavioral data.

^dPercentage calculated based on the number of participants who reported having had vaginal, oral, and/or anal sex in the past month.

^{*} Denotes significant differences between on-site bundled rapid HIV/HCV testing and standard of care at p<.05

SD = Standard Deviation; FQHC = Federally qualified health center,

Table 2.

Outcomes by Assigned Study Group, Intent-to-treat Analysis of Study Completers

	On-site Bundle HIV/HCV Rapid Testing	Standard of Care	Unadjusted Risk Ratio ^a (95% CI)	Adjusted Risk Ratio ^b (95% CI)	p-value
Primary Outcome					
Self-reported receipt of both HIV and HCV test results	45 (69)	13 (19)	3.7 (2.2 to 6.2)	3.6 (2.2 to 6.1)	<0.001<0.001
Other testing outcomes					
Directly observed receipt of both HIV/HCV test results	57 (88) ^d	--	--	--	--
New HIV diagnoses	0 (0)	0 (0)	--	--	--
New HCV diagnoses	7 (11)	1 (1)	--	--	0.03
Secondary Outcomes					
Use of any drugs	25 (38)	35 (51)	0.8 (0.5 to 1.1)	0.7 (0.5 to 1.1)	0.11
Injected drugs	8 (12)	8 (12)	1.0 (0.9 to 1.1)	1.0 (0.9 to 1.1)	0.97
Shared needles	1 (2)	2 (3)	0.5 (0.1 to 5.8)	0.4 (0.0 to 5.4)	0.52
Unprotected intercourse	16 (25)	14 (20)	1.2 (0.6 to 2.3)	1.2 (0.6 to 2.2)	0.58
Linkage to care ^c	7 (100)	1(100)	--	--	--

^aObtained from Poisson regression models, which only included a binary variable indicating the study group assignment as covariate.^bObtained from Poisson regression models, which also included stratification variables and predictors of retention as covariates.^cPercentage calculated among participants who reported being diagnosed with HCV during the follow-up period.^dNumber of patients who received both HIV and HCV test results, per study logs. This measure is not available for control group participants.

-- Data not available or relative risk ratio could not be calculated because there were too few cases.

Table 3:
Sensitivity Analysis Imputing Outcomes for Participants Who Did Not Complete Follow-Up Assessment

	Unadjusted Risk Ratio ^a	Adjusted Risk Ratio ^b	p-value
Primary Outcome			
Self-reported receipt of both HIV and HCV test results	3.6 (2.1 to 6.2)	3.6 (2.1 to 6.1)	<0.001
Secondary Outcomes			
Use of any drugs	0.8 (0.5 to 1.1)	0.7 (0.5 to 1.1)	0.11
Injected drugs	1.0 (0.8 to 1.2)	1.0 (0.8 to 1.2)	0.83
Shared needles	0.5 (0.0 to 5.7)	0.4 (0.0 to 5.0)	0.50
Unprotected intercourse	1.2 (0.6 to 2.3)	1.2 (0.6 to 2.3)	0.61

All analyses were conducted after imputing outcomes for participants who were lost to follow-up, thus the sample size was n=162.

We assumed that participants who were lost to follow-up experienced the least favorable outcome (i.e., they did not test for HIV/HCV or that they used drugs).

^aObtained from Poisson regression models, which only included the study group (treatment vs. control) as covariate.

^bObtained from Poisson regression models, which also included stratification variables as covariates.