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Safety and Effectiveness of Same-Day *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Screening and Treatment among Gay, Bisexual, Transgender, and Homeless Youth in Los Angeles, California and New Orleans, Louisiana

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Abstract

Background: Gay, bisexual, transgender, and homeless youth are at risk for sexually transmitted infections (STIs). As part of an adolescent HIV prevention study, we provided same-day *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) testing and treatment. We aimed to evaluate the feasibility and effectiveness of same-day CT and NG treatment on the proportion of participants receiving timely treatment.

Methods: We recruited adolescents with high sexual risk behaviors aged 12–24 years from homeless shelters, lesbian, gay, bisexual, and transgender organizations, and community health centers in Los Angeles, California and New Orleans, Louisiana from May 2017 to June 2019. Initially, participants were offered point-of-care pharyngeal, rectal, and urethral/vaginal CT and NG testing and referral to another clinic for treatment. After March 2018 in Los Angeles and November 2018 in New Orleans, we provided same-day treatment (and partner treatment packs) for study participants. We measured the proportion of participants who received treatment within 30 days and the median time to treatment. We collected frequency of partner treatment and any reported adverse treatment-related events.

Results: The proportion of participants receiving same-day CT and NG treatment increased from 3.6% (5/140) to 21.1% (20/95) [17.5%, 95% CI 9.2, 26.9] after implementation of same-day testing and treatment. The median time to treatment decreased from 18.5 to 3 days. Overall, 36

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Conflict of Interest statement

The authors do not have a commercial or other association that might pose a conflict of interest

participants took a total of 48 partner treatment packs. There were no reported treatment-related adverse events.

Conclusions: Providing STI treatment to adolescents at the same visit as testing is safe, feasible, and can increase the proportion of individuals receiving timely treatment.

Short Summary:

Providing same day *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing and treatment for adolescents in Los Angeles, CA and New Orleans, LA was feasible and increased timely treatment.

Keywords

Chlamydia trachomatis; *Neisseria gonorrhoeae*; testing; treatment; adolescents

Introduction:

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) are the most common reported sexually transmitted infectious diseases. According to the Centers for Disease Control and Prevention (CDC), young people aged 15–24 years account for half of all new sexually transmitted infections (STIs) each year.¹ Timely and appropriate treatment of CT and NG is important to reduce the risk of infertility and pelvic inflammatory disease and reduce transmission to sex partners.¹

Gay, bisexual, and transgender youth may also be at greater risk for STIs. Those populations often report risk-taking behaviors such as higher number of sex partners, failure to use condoms consistently and correctly, and less frequent STI screening due to concerns about confidentiality and stigma.² Negative attitudes towards homosexuality, poor mental health, and substance abuse are also associated with increased likelihood of condomless anal sex and increased number of sex partners among this population.³ One study in San Francisco found that street-recruited youth were significantly more likely than clinic-recruited youth to engage in survival sex, have multiple partners, partners who inject drugs, or partners who are HIV-infected.⁴

Standard CT and NG nucleic acid amplification testing does not provide clinics and patients with immediate results, thus creating a need for multiple visits for testing and treatment.⁵ A previous study found that 40% of female adolescents with untreated CT and NG infections were lost to follow-up after leaving an emergency department after testing.⁶ Additionally, a recent study found that only 60% of STI medications prescribed in a pediatric emergency department are filled in the pharmacy once the patient leaves.⁷ In clinics in California, prescription fill rates were lowest at 47% for patients age 18 years and younger, demonstrating the need for on-site treatment, especially among younger patients.⁸

The delay between STI testing and treatment may also cause many health care providers to rely on empiric treatment to avoid potential loss-to-follow-up for untreated patients. However, empiric treatment can lead to over-treatment of STIs, potentially perpetuating drug resistance.^{9,10} One study found a significant reduction in unnecessary antibiotic treatment

for CT and NG in patients receiving a point-of-care STI test compared to those receiving standard testing in an emergency department.¹¹

Point-of-care community-based STI testing presents an opportunity to increase access to STI screening and reduce STI transmission among adolescents and young adults, particularly high-risk adolescents who do not traditionally have access to sexual health services.¹² Many previous studies evaluating testing and treatment of STIs have been conducted in emergency departments or outside the United States, and few focus on testing and treatment among gay, bisexual, transgender, or homeless youth in community health settings^{6,7,8}. As part of the Adolescent Medicine Trials Network for HIV/AIDS Interventions^{13,14} we provided same-day CT and NG testing and treatment among a sample of adolescents in Los Angeles and New Orleans. We aimed to evaluate if providing same-day testing and treatment would increase the proportion of participants receiving treatment and reduce the overall time to treatment.

Materials and Methods:

Recruitment

From May 2017 to June 2019, we recruited gay, bisexual, and transgender youth, youth with a history of mental health disorders, and youth with a history of incarceration aged 12–24 years old. We recruited participants from homeless shelters, lesbian, gay, bisexual, transgender organizations, community health centers, and using social media and online dating apps such as Grindr, Tinder, Jack'd, Scruff, and Chappy in Los Angeles, California and New Orleans, Louisiana. We referred eligible participants from social media and dating sites to one of our existing sites for enrollment. We determined study eligibility using a questionnaire which measured demographic information and risk behavior of participants, such as illicit drug use, needle sharing, condomless sex, and number of sex partners. Answers to the questionnaire were weighted, and if a participant had an overall risk score ≥ 7 , they were enrolled in the study.¹⁵

STI testing procedures

Participants were enrolled in the study for 24 months. Every four months, participants were scheduled for a study visit where they would self-collect pharyngeal, rectal, and urethral or vaginal samples for CT and NG testing. We tested samples using the Cepheid GeneXpert® CT/NG Assay (Sunnyvale, CA), which is a real-time, PCR test which provides results in 90 minutes.¹⁶ It is Food and Drug Administration approved for urethral samples and has also been verified using pharyngeal and rectal swabs in accordance with the Clinical Laboratory Improvement Amendments act.¹⁷ Study staff instructed participants on self-collecting specimens using a fleshlight and by providing oral instructions. We allowed participants to opt out of any test they did not want to receive. We recorded STI screening and treatment results in the mobile application CommCare (Dimagi, Cambridge, MA).

STI treatment procedures

Before March 2018 in Los Angeles and November 2018 in New Orleans, following a positive CT or NG test, participants were referred to a local clinic or their primary care

doctor for treatment. All partner medical clinics agreed to provide STI treatment in accordance with CDC recommendations.¹⁸ After March 2018 in Los Angeles and between November 12th through February 28th in New Orleans, participants were offered same-day treatment and expedited partner therapy packs by our study staff.

We encouraged participants to wait the 90 minutes for their test results to receive immediate treatment. If a participant chose not to stay, our study team called the participant following a positive result to schedule a follow-up visit for treatment. At the follow-up visit, we offered participants a treatment packs for themselves, and up to ten treatment packs for their recent sex partners. Upon distribution of treatment, we informed the participants of any potential side effects and instructed the participants to call the study physician with any questions. Additionally, participants still had the option to receive treatment with their primary care provider, if they had one, or a referral to a local medical clinic. We contacted participants to confirm treatment with their primary care provider, and if unable to reach the participant, we would request medical records from the clinic.

We treated vaginal, urethral, and pharyngeal CT infections with a one gram oral dose of azithromycin, while we treated rectal CT infections with 100 mg oral doxycycline twice daily for seven days. We treated NG infections with one dose of 400 mg oral cefixime and one gm oral azithromycin. For NG infections accompanied with a rectal CT infection, we treated with 100 mg oral doxycycline twice daily for seven days and one dose of 400 mg oral cefixime. In addition to medication, the treatment packs contained the name of the medication, dose, detailed instructions on how to take the medication, contact information for both the study doctor and interviewer, the medication lot number, and the medication expiration date.

Measurements

We compared demographics of our population including birth sex, gender identity, race/ethnicity, education, employment, type of insurance, as well as location of testing and if same-day treatment was received. We recorded the number of partner treatment packs taken by participants and recorded any reported adverse effects to the CT or NG medications in the database.

Statistical Analysis

We measured the proportion of participants who received same-day treatment and treatment within 30 days for a positive CT or NG infection before and after offering same-day testing and treatment by location (Los Angeles or New Orleans), using a Chi-Square test for significance. An occurrence of an STI would be considered if any one of the 6 STI tests (CT/NG vaginal/urethral, rectal, pharyngeal) was reactive. Due to a skewed distribution, we chose to compare median days to treatment by each demographic characteristic, testing for differences using the Mann-Whitney test. Because those methods do not account for repeated measures, in the analysis we chose to include only those participants who tested positive once in the available data. All analysis was performed using SAS 9.4.

The University of California Los Angeles Institutional Review Board (UCLA IRB #16-001674-AM-00006) and Tulane University Review Board (Tulane IRB #1033876) approved

the study protocol. Any protocol deviations or indications of adverse events were reported to the Institutional Review Board. The study was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) on April 28, 2017 (#NCT03134833).

Results:

We recruited 235 participants with positive CT or NG infections. Of those participants, 126 (53.6%) had CT infections only, 79 (33.6%) had NG infections only, and 30 (12.7%) had coinfections with CT and NG. We found similar proportions of infections before and after offering same-day treatment. Before offering same-day testing and treatment, the proportion of individuals with re-infections was 20%, while the proportion of participants with re-infections after providing same-day testing and treatment was 12% (prevalence ratio .60, 95% CI 0.33–1.09).

Table 1 shows demographic information for the study participants including birth sex, gender identity, race/ethnicity, education, employment, type of insurance, and homelessness as well as the median days to treatment for each demographic breakdown. Additionally, 110 participants (46.8%) reported previous illicit drug use in their lifetime and only 91 (39.2%) reported 100% condom usage. The median number of sex partners in our sample was 3 [IQR 1–4 partners].

Figure 1 shows the proportion of adolescents aged 14–24 years who received same-day treatment or treatment within 30 days for CT or NG infections in Los Angeles and New Orleans before and after we provided same-day testing and treatment as part of our study. The overall proportion of participants receiving same day treatment increased from 3.6% to 21.1% (17.6%, 95% CI 9.2–26.9%) after offering same-day testing and treatment. In Los Angeles, the proportion of participants receiving same-day treatment increased from 0% (0/27) to 23.2% (19/82). In New Orleans, the proportion increased from 4.4% (5/114) to 7.7% (1/13).

Only 36 (37.9%) participants in our study took a total of 48 partner treatment packs (median = 1 pack taken per participant [range 1–3 packs]). In Los Angeles, 31 participants took a total of 43 partner treatment packs while in New Orleans, 5 participants took a total of 5 partner treatment packs.

There were no reported adverse effects to any of the medications.

Discussion

As part of a large adolescent behavioral trial to reduce sexual risk behaviors, we evaluated the impact of same-day testing and treatment for CT and NG infections. We measured the proportion of adolescents receiving treatment for CT and NG in Los Angeles and New Orleans. Providing same-day CT and NG treatment after testing significantly increased the proportion of participants receiving same-day treatment in Los Angeles. Additionally, the overall median days to treatment was reduced by at least one half in both locations. However, same-day treatment was only provided in New Orleans for about three months due to limited antibiotic supply. Additionally, many participants in New Orleans lived in a

narrower geographic area, allowing for more referrals to accessible health clinics. As only 13 participants had active infections during the time same-day testing and treatment was offered, our analysis does not have statistical significance for New Orleans.

Adolescents present challenges for follow-up and timely treatment.¹⁹ In a previous study in a teen health center, one third of patients were not treated for STIs for more than seven days.⁸ In our study, the median time to treatment was over 2 weeks in both New Orleans and Los Angeles before same-day testing and treatment was offered. Previous studies have implemented new strategies to try and increase STI screening and treatment among hard-to-reach populations. In San Francisco, offering field delivered therapy was successful in increasing treatment completion for CT and NG infections among individuals who were unable or unlikely to visit a clinic for treatment.²⁰ Studies outside the United States in Botswana, the Democratic Republic of Congo, Haiti, South Africa, and Vietnam, screened individuals for CT, NG, and TV using point-of-care testing and found a high acceptability of screening and feasibility of same-day treatment.²¹ Another study in London found that using point-of-care STI testing greatly reduced the time from clinic attendance to treatment for asymptomatic CT and NG infections and notification of results.²²

Very few studies evaluating the use of the Cepheid GeneXpert ® for point-of-care same-day testing and treatment of STIs have occurred in the United States. A pilot study among students used the Cepheid GeneXpert ® to test for CT and NG and provided same-day treatment as needed.²³ They found high acceptability of the point-of-care test, however, their study was limited by a small sample size as only 3 students were positive for CT. Further implementation science research is needed to expand the use of same-day STI testing and treatment, particularly among gay, bisexual, transgender, and homeless youth.

Expedited partner therapy is a proven health care practice that allows clinicians to give patients medications or prescriptions to distribute to their partners, especially if the partner is unable or unlikely to seek care in a timely matter. The American Academy of Family Physicians and the CDC supports clinicians in the treatment of sex partners of individuals diagnosed with CT or NG.²⁴ A previous study found that providing expedited partner therapies is less costly and treats more partners than standard partner referrals.²⁵ In our study, while we did potentially treat 48 sex partners with expedited partner therapy packs, only about one third of the participants offered treatment packs for their recent sex partners took them. Greater efforts are needed to increase STI treatment for all sex partners, allowing for quicker treatment and prevention of future spread of transmission.

Our study was limited by modest sample sizes, particularly for participants receiving same-day treatment in New Orleans. We also used convenience sampling as participants were recruited through online advertising and advertising in community centers. That may have led to some selection bias resulting in participants who are more likely to engage in the health care system or seek STI testing and treatment. Additionally, our sample may not be representative of all lesbian, gay, bisexual, transgender, or homeless adolescents in Los Angeles and New Orleans.

While offering same-day CT and NG treatment significantly improved the time to treatment and proportion of participants receiving treatment, some participants remained untreated if they were not able or willing to wait 90 minutes for the test results. Work must continue to be made to improve point-of-care STI tests and reduce the time from testing to results in order to increase treatment for all individuals. Continuing to reduce the time-to-treatment is important to prevent future transmission of CT and NG infections. We found that providing same-day testing and treatment for CT and NG is safe, feasible, and can increase the proportion of high-risk adolescents in community health settings receiving timely treatment.

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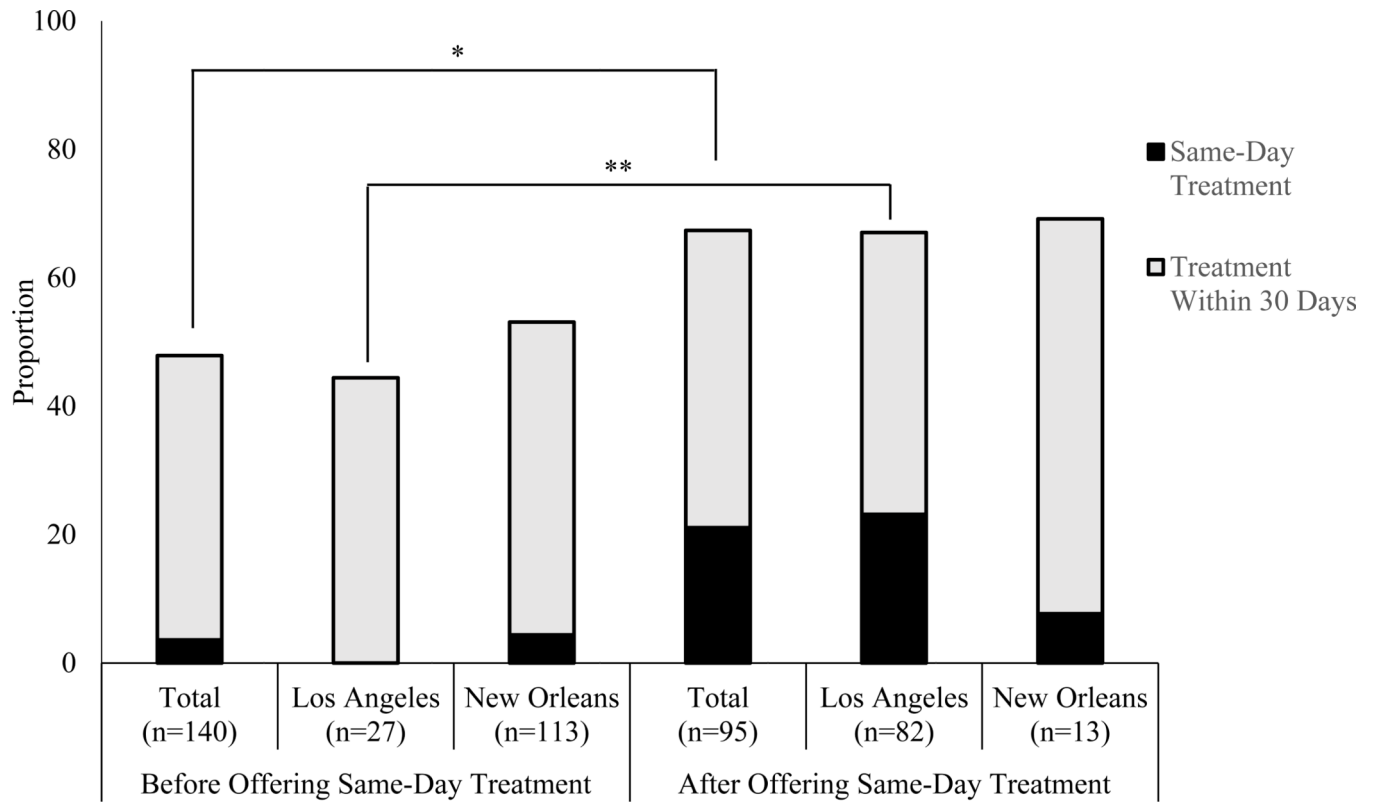
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*Statistically significance $p < .05$

**Statistically significance $p < .01$

Figure 1.

Proportion of adolescents aged 14–24 years receiving same-day treatment for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) or treatment within 30 days of testing in Los Angeles and New Orleans from May 2017 to June 2019.

Table 1.

Select characteristics, including demographic information, location of testing, and median days to treatment for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) among adolescents age 14–24 years from May 2017 to June 2019, Los Angeles and New Orleans.

	N participants (%)	Median time to treatment before same-day treatment N days [interquartile range] (n=140)	Median time to treatment after same-day treatment N days [interquartile range] (n=95)	P-Value
Overall	235	18.5 [5.0,46.5]	3.0 [0.0,12.0]	<.01
Location				
Los Angeles	109 (46.4%)	22.0 [6.0,54.0]	3.0 [0.0,13.0]	<.01
New Orleans	126 (53.6%)	15.0 [4.0,44.0]	7.5 [2.0,12.0]	0.05
Birth Sex				
Male	190 (80.9%)	15.0 [5.0,44.0]	3.0 [0.0,21.0]	<.01
Female	45 (19.1%)	27.5 [3.0,59.0]	2.0 [1.0,8.0]	0.04
Gender Identity				
Men who have sex with men	129 (54.9%)	10.0 [5.0,32.0]	3.5 [0.0,25.0]	0.01
Transgender/gender non-conforming	24 (10.2%)	10.0 [2.0,15.0]	1.0 [0.0,2.0]	0.06
Heterosexual Men	38 (16.2%)	31.0 [8.0,65.5]	9.0 [5.0,32.0]	0.34
Heterosexual Women	25 (10.6%)	25.0 [3.0,62.0]	4.5 [0.5,11.0]	0.33
Non-heterosexual female	19 (8.1%)	30.0 [3.0,59.0]	3.0 [1.0,5.0]	0.17
Race/Ethnicity				
African American	151 (64.3%)	16.0 [4.0,43.0]	5.0 [1.0,10.0]	<.01
Asian/Hawaiian Pacific Islander/ American Indian/Alaska Native	13 (5.5%)	59.0 [10.0,83.0]	0.0 [0.0,21.0]	0.4
Latino	48 (20.4%)	42.0 [15.5,71.0]	3.5 [0.0,10.0]	0.29
White	19 (8.1%)	10.5 [3.0,51.5]	17.5 [0.5,42.5]	.99
Other Race	4 (1.7%)	18.5 [7.0,30.0]	3.0 [3.0,3.0]	0.48
Education				
Below high school	62 (26.4%)	15.0 [4.0,31.0]	1.0 [0.0,31.0]	0.08
High school diploma/equivalent	58 (24.7%)	15.5 [3.0,56.5]	5.0 [2.0,11.0]	0.13
Some higher education	98 (41.7%)	22.0 [6.0,44.0]	3.0 [0.5,11.0]	<.01
Completed Higher education	17 (7.2%)	45.0 [6.0,84.0]	1.0 [1.0,12.0]	0.32
Employment				
Employed	103 (44.4%)	10.0 [3.0,34.0]	5.0 [0.0,12.0]	0.04
Unemployed	63 (27.2%)	27.5 [6.0,85.5]	5.0 [1.0,32.0]	0.05
Student	66 (28.4%)	19.0 [3.0,30.0]	1.5 [0.5,4.5]	<.01
Insurance				
Medicaid	90 (39.5%)	7.0 [3.0,30.0]	5.0 [1.0,31.0]	0.37
Medicare	27 (11.8%)	26.0 [10.0,54.0]	7.0 [0.0,21.5]	0.11
Private	47 (20.6%)	10.0 [4.0,66.0]	3.0 [1.0,7.0]	0.04
Other	1 (0.4%)	54.0 [54.0,54.0]	NA	NA

	N participants (%)	Median time to treatment <u>before</u> same-day treatment N days [interquartile range] (n=140)	Median time to treatment <u>after</u> same-day treatment N days [interquartile range] (n=95)	P-Value
Uninsured	61 (26.8%)	30.0 [8.5,57.0]	1.0 [0.0,9.0]	<.01
Been Homelessness in Lifetime				
No	122 (51.9%)	24.5 [4.0,49.0]	2.5 [0.0,7.0]	<.01
Yes	113 (48.1%)	14.5 [5.0,43.0]	5.5 [1.0,32.0]	0.29
Been Homeless Within the Past 30 Days				
Recent – No	161 (69.1%)	34.0 [5.0,43.5]	3.0 [0.0,9.0]	<.01
Recent – Yes	72 (30.9%)	12.0 [4.5,52.5]	5.5 [1.5,33.0]	0.39

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