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Accuracy of Presumptive Gonorrhea Treatment for Gay, Bisexual, and Other Men Who Have Sex with Men: Results from a Large Sexual Health Clinic in Los Angeles, California

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Abstract

Purpose: This study analyzed the accuracy of presumptive gonorrhea treatment in a sexual health clinic serving primarily gay, bisexual, and other men who have sex with men (MSM). Treating suspected gonorrhea before laboratory confirmation can reduce symptoms and transmission; however, this strategy can overtreat uninfected individuals, which may promote antimicrobial resistance. We identified differences in accuracy of gonorrhea presumptive treatment by site of infection and presence of signs or symptoms.

Methods: We conducted a cross-sectional study of gay, bisexual, and other MSM who were treated presumptively for gonorrhea at the Los Angeles LGBT Center between February and July 2015. We calculated positivity of treated patients, proportion of infections treated, and positive predictive value (PPV) of treating gonorrhea presumptively based on signs, symptoms, or exposure at the urethral, rectal, or pharyngeal site.

Results: Of 9141 testing visits, presumptive treatment was provided at 1677 (18%). Overall, gonococcal infections were identified at 31% (n=527) of visits where presumptive treatment was provided, compared to 9% (n=657) of visits without presumptive treatment (P<0.01). Forty-five percent of gonococcal infections were treated presumptively, and treatment was provided at 14% of gonorrhea-negative visits. Seventy-eight percent of urethral, 54% of rectal, and 35% of pharyngeal infections were treated presumptively. PPV was highest for genitourinary signs.

Conclusion: Approximately one-third of gay, bisexual, or other MSM treated presumptively for gonorrhea at a sexual health clinic tested positive for gonorrhea. These findings highlight the potential contribution of point-of-care tests in reducing overtreatment resulting from presumptive treatment.

Keywords: bisexual, clinical research, epidemiology, gay, men who have sex with men, sexually transmitted infections

Introduction

GONORRHEA CONTINUES to cause significant morbidity in the United States, particularly among gay, bisexual, and other men who have sex with men (MSM). In 2014, gonorrhea was the most commonly reported bacterial sexually transmitted infection (STI) among MSM testing at clinics participating in the Centers for Disease Control and Prevention's (CDC) STD Surveillance Network (SSuN), with a median positivity of 19.2%, and it is moderately prevalent even outside clinical settings.^{1,2} Treating patients based on a pre-

sumptive STI diagnosis before laboratory results are available can hasten symptom resolution, prevent transmission, and reduce the need for patients to return for treatment.³ However, providing antibiotics to patients who test negative may contribute to increasing antimicrobial resistance.⁴

An estimated 90% of urethral gonococcal infections among MSM are symptomatic, compared to about 16% of rectal gonococcal infections and very few pharyngeal gonococcal infections.^{5,6} Among MSM, management of extragenital gonorrhea (i.e., rectal and pharyngeal infections) is particularly important because it is more common than urethral

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gonorrhea.^{6,7} Furthermore, when extragenital infections do produce symptoms, they are nonspecific.^{6,8} We hypothesize that this may contribute to a lower accuracy of presumptive treatment compared to urethral infections.

Although presumptive treatment is a key component of STI management in populations with high disease burden, data on the gonorrhea positivity among MSM treated presumptively are limited. In a study of HIV-positive MSM ($n=205$), Scott et al.⁹ found that 63% (27/43) of those treated presumptively were positive for gonorrhea (any anatomic site), compared to only 16% (26/162) of those who were not treated presumptively. In another study by Davis and Goldstone,¹⁰ 26 patients were treated presumptively based on clinical diagnoses of proctitis; of those, 35% ($n=9$) tested positive for gonorrhea.

The purpose of this study was to examine the prevalence of and factors associated with gonorrhea positivity among gay, bisexual, and other MSM treated presumptively compared to those not treated presumptively in a busy urban U.S. STI program. The objectives of this study were threefold: determine (1) the proportion of treated patients who tested positive, (2) the proportion of infections treated, and (3) the positive predictive value (PPV) of treating gonorrhea presumptively based on signs, symptoms, or exposure at the urethral, rectal, or pharyngeal site.

Methods

This was a cross-sectional study using existing medical records collected as part of routine clinical care provided at the Los Angeles LGBT Center (the Center). The Center, a community-based organization, provides a broad spectrum of services for the lesbian, gay, bisexual, and transgender communities. The Center provides free STI testing and treatment services to approximately 15,000 clients each year.

Each patient who presents for STI screening undergoes a counselor-administered risk assessment of demographics, sexual behaviors, and symptoms. The patient self-collects rectal and urine samples for gonorrhea and chlamydia nucleic acid amplification tests (NAATs), which are performed using APTIMA Combo 2[®] Assay (Hologic Gen-Probe, San Diego, CA). Pharyngeal samples are collected by clinical care providers. Male patients are encouraged to have urethral, rectal, and pharyngeal gonorrhea tests, but may choose not to be tested or examined at all sites.

Patients who report symptoms to the counselor are then triaged to a clinician for further evaluation. The clinician records symptoms and performs a targeted physical examination to identify signs of infection. Digital rectal or anoscopic examination is not performed. Clinicians determine whether to prescribe same-day presumptive treatment or wait for test results by evaluating a patient's medical and sexual history, according to the CDC's gonorrhea treatment guidelines.⁸ Same-day presumptive treatment effective against gonorrhea and chlamydia—dual therapy of azithromycin and ceftriaxone—is provided to patients with clinical signs consistent with gonorrhea and/or chlamydia, those with known exposure to gonorrhea, and to symptomatic patients who are unlikely to return for follow-up evaluation or treatment.⁸ Despite the finding that most pharyngeal gonorrhea is asymptomatic,⁶ clinicians noted that, at this clinic, treatment is provided to MSM who report condomless oral sex with a

partner of unknown STI status and have pharyngitis without other symptoms that support an alternative etiology such as allergies or viral upper respiratory tract infection.

Symptoms, signs, and International Classification of Diseases, Ninth Revision (ICD)-9 codes were abstracted from the electronic medical record (EMR). In this analysis, patients were considered “symptomatic” if they had urethral discharge, dysuria, testicular pain, or a clinical diagnosis of urethritis; anal discharge or a clinical diagnosis of proctitis; or a clinical diagnosis of pharyngitis. Patients were considered to have “signs” if they had urethral or rectal physical examination findings. Exposed, asymptomatic patients were those with an ICD-9 code for exposure to gonorrhea or exposure to venereal disease, and no signs or symptoms. Inclusion criteria were as follows: cisgender MSM aged 18 years or older who tested for gonorrhea of the urethra, rectum, and/or pharynx between February and July 2015. Participants are identified in the dataset as cisgender MSM based on three criteria: (1) assigned male sex at birth, (2) current gender identity of male, and (3) gay or bisexual sexual orientation, or other sexual orientation and a male sex partner within the past year.

Statistical analysis

Visits were the units of analysis. The term “patient” is used to refer to unique visits, rather than unique individuals; thus, if a unique individual had multiple visits, each visit would be included separately and considered a “patient.” Demographic differences associated with presumptive treatment among those testing positive were examined using bivariate logistic regression (0.05 α level). A one-tailed Z-test of proportions (0.05 α level) was performed to test whether patients treated presumptively had higher gonorrhea positivity than patients who did not receive presumptive treatment. The PPV was the probability that a patient treated presumptively for gonorrhea tested positive for gonorrhea, calculated overall and by treatment indication. Accurate presumptive treatment referred to treating people presumptively, who then tested positive for gonorrhea. To determine the overall proportion of patients treated presumptively, who tested positive for at least one infection susceptible to the treatment regimen, the chlamydia positivity among gonorrhea negative patients was calculated. Data were analyzed using SAS 9.4 (SAS Institute Inc., Cary, NC).

Ethics

The study received approval from the University of California, Los Angeles South General Institutional Review Board (SGIRB) (IRB No.: 00004474; Project No.: 16-000240). A waiver of informed consent was granted by the IRB because the analysis was limited to secondary data collected as part of clinical care.

Results

During the study period, there were 9141 visits among 6756 unique gay, bisexual, and other MSM testing for gonorrhea (Table 1). At more than half of visits, patients were 30 years or older. The sample was racially and ethnically diverse with 47% White, 31% Hispanic, 8% Black or African American, and 13% other race/ethnicity represented among the visits. At 1184 visits (13%), there was a positive

TABLE 1. PATIENT CHARACTERISTICS AT VISITS WITH AND WITHOUT GONORRHEA PRESUMPTIVE TREATMENT ($n=9141$), FEBRUARY 2015–JULY 2015

	<i>Presumptive treatment provided</i>		<i>Presumptive treatment not provided^a</i>		<i>Total</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>N</i>	<i>%</i>
Gender						
Male	1677	100	7464	100	9141	100
Age group						
<25 years	292	17	1431	19	1723	19
25–29 years	432	26	2108	28	2540	28
30–39 years	533	32	2296	31	2829	31
40+ years	420	25	1629	22	2049	22
Race/ethnicity						
White	797	48	3518	47	4315	47
Hispanic	506	30	2355	32	2861	31
Black or African American	174	10	553	7	727	8
Other	199	12	1032	14	1231	13
Unknown/unreported	1	0.1	6	0.1	7	0.1
Sexual orientation						
Gay/homosexual	1464	87	6310	85	7774	85
Bisexual	173	10	956	13	1129	12
Other	35	2	183	2	218	2
Unknown/unreported	5	0.3	15	0.2	20	0.2
Gonorrhea result ^b						
Positive, any site	527	31	657	9	1184	13
Urethral	266/1647	16	74/7284	1	340	4
Rectal	397/1569	25	337/7183	5	734	8
Pharyngeal	222/1590	14	421/7228	6	643	7
Negative at all sites tested	1150	69	6807	91	7957	87
Prevalence of signs/symptoms ^c						
Genitourinary signs	240	14	3	0.04	243	3
Genitourinary symptoms	869	52	95	1	964	11
Rectal signs	11	1	9	0.1	20	0.2
Rectal symptoms	155	9	22	0.3	177	2
Pharyngitis	49	3	28	0.4	77	1
Asymptomatic, exposed	591	35	401	5	992	11
Total	1677	100	7464	100	9141	100

^aThis includes individuals who tested positive for gonorrhea and were subsequently treated, as well as those who tested negative.

^bMale patients are encouraged to have urethral, rectal, and pharyngeal gonorrhea tests, but may choose not to be tested or examined at all sites.

^cCategories are not mutually exclusive.

gonorrhea result at one or more anatomic sites. Presumptive treatment was provided at 1677 visits (18%) from 1514 unique individuals. The majority of presumptive treatment visits included gonorrhea tests from all anatomic sites; however, 30 (2%) had no urethral test, 108 (6%) had no rectal test, and 87 (5%) had no pharyngeal test. Patients treated presumptively were significantly more likely to test positive for gonorrhea compared to patients who were not treated presumptively ($P<0.01$). Overall, gonococcal infections were identified at 31% ($n=527$) of the 1677 visits where presumptive treatment was provided, compared to 9% ($n=657$) of the 7464 visits with no presumptive treatment.

Bivariate associations of demographic characteristics on presumptive treatment among those testing positive for gonorrhea found a significant association between presumptive treatment and age ($P<0.01$), but not sexual orientation ($P=0.06$) or race/ethnicity ($P=0.10$). Specifically, gonorrhea positive patients who were 40 years or older were more likely to be treated presumptively compared to those who were younger than 25 years.

Overall, 45% of gonococcal infections were treated presumptively (Table 2). Extragenital infections were more common than urethral infections, and were less likely to be treated presumptively. The proportion of infections treated differed by anatomic site. Seventy-eight percent of urethral infections, 54% of rectal infections, and 35% of pharyngeal infections were treated presumptively. Presumptive treatment was provided at 14% ($n=1150$) of visits where all gonorrhea tests were negative.

Controlling for site of infection, the PPV for indications of presumptive treatment were highest for genitourinary signs (56%), genitourinary symptoms (29%), and rectal symptoms (28%) (Table 3). Rectal signs and pharyngitis were less common and less predictive of infection. Symptoms or signs may be caused by an infection other than gonorrhea. Of presumptive treatment visits where no gonococcal infection was identified ($n=1150$), chlamydial infections were identified at 172 (15%) (Table 4). Therefore, an infection susceptible to the antibiotic regimen was identified at 42% of presumptive treatment visits. At visits where neither gonococcal nor

TABLE 2. PROPORTION OF GONOCOCCAL INFECTIONS TREATED PRESUMPTIVELY, BY ANATOMIC SITE, FEBRUARY 2015–JULY 2015

	<i>Treated presumptively</i>		<i>Total N</i>
	<i>n</i>	<i>%</i>	
Positive, any site	527	45	1184
Urethral	266	78	341
Rectal	397	54	734
Pharyngeal	222	35	643
Negative all sites	1150	14	7957

chlamydial infection was identified, 9 (0.9%) included a positive test for current syphilis infection and 9 (0.9%) included an HIV positive test. At 960 presumptive treatment visits (57% of all presumptive treatment visits), no infection was identified.

Discussion

Our study found that gonorrhea positivity was higher among visits with presumptive treatment (31%) compared to those without presumptive treatment (9%). The accuracy of presumptive gonorrhea treatment varied by anatomic site of gonorrhea and presence of signs or symptoms. The PPV was highest for genitourinary signs, but given the substantial burden at extragenital sites, and the low PPV of signs and symptoms at these sites, other strategies beyond presumptive treatment are needed to reduce the potential for overtreatment.

The finding that gonococcal infections were identified at only one third of visits where presumptive treatment was provided highlights the potential for point-of-care tests to reduce this overtreatment. Rapid point-of-care tests would allow providers to prevent unnecessary provision of antibiotics and reduce the issue of loss to follow-up for individuals who need to return for treatment. As of 2017, point-of-care gonorrhea/chlamydia tests have only been approved by the Food and Drug Administration for use in genitourinary infections.¹¹ Despite this, some tests have been validated for use at extragenital sites by various laboratories and thus can be

TABLE 3. POSITIVE PREDICTIVE VALUE OF SIGNS, SYMPTOMS, AND EXPOSURE AT VISITS WHERE PRESUMPTIVE GONORRHEA TREATMENT WAS PROVIDED, (*n* = 1677), FEBRUARY 2015–JULY 2015

<i>Indication^a</i>	<i>Gonorrhea positive (controlling for infection site)</i>	<i>Total with indication N</i>	<i>PPV %</i>
	<i>n</i>		
Genitourinary symptoms	256	869	29
Genitourinary signs	134	240	56
Rectal symptoms	43	155	28
Rectal signs	2	11	18
Pharyngitis	3	49	6
Asymptomatic, exposed	154	591	26

^aCategories are not mutually exclusive. All who had genitourinary signs also reported genitourinary symptoms.

TABLE 4. SEXUALLY TRANSMITTED INFECTION TEST RESULTS AND TREATMENT INDICATIONS AT VISITS WHERE PRESUMPTIVE TREATMENT WAS PROVIDED AND GONORRHEA TEST WAS NEGATIVE AT ALL ANATOMIC SITES (*n* = 1150), FEBRUARY 2015–JULY 2015

<i>Treatment indication^a</i>	<i>Chlamydia positive</i>		<i>No infection identified</i>		<i>Total^b</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>N</i>	<i>%</i>
Genitourinary symptoms	90	52	462	48	557	48
Genitourinary signs	14	8	77	8	92	8
Rectal symptoms	20	12	85	9	109	9
Rectal signs	1	1	8	1	9	1
Pharyngitis	3	2	41	4	45	4
Asymptomatic, exposed	60	35	369	38	437	38
Total	172	100	960	100	1150	100

^aCategories are not mutually exclusive.

^bEighteen patients who tested negative for gonorrhea and chlamydia, and positive for syphilis (*n* = 9) or HIV (*n* = 9) are included in the total column.

used by laboratories that meet all regulatory requirements for an off-label procedure.^{1,12} In settings where prevalence of gonorrhea and chlamydia infections is high, especially at extragenital sites where symptomatology has poor predictive value, point-of-care tests would be useful. Currently, few clinics use point-of-care gonorrhea/chlamydia tests, but these tests should be adopted widely, particularly in clinics serving MSM. A systematic review of point-of-care testing for gonorrhea suggests it is feasible, acceptable, and cost-effective in the settings where it has been studied, but more observational data are needed to determine how wait time, cost to patient, and initial cost to a clinic may influence adoption in clinics.¹³

The strengths of this study included the large sample size, a study population with high incidence of gonorrhea, and the ability to investigate signs, symptoms, and exposure as predictors of gonorrhea positivity. Studying both self-reported symptoms and provider-determined signs enabled us to examine the trade-off between syndromic algorithms with a high PPV (treating all with observed urethral discharge) versus those that result in a larger number of infections being treated presumptively (treating all who report symptoms).

Limitations

This study had several key limitations. The Center does not employ laboratory staff trained to perform gram stains and does not presently have the capability to perform other point-of-care gonorrhea testing. Having either would likely increase the proportion of urethral infections treated and decrease overtreatment. Prevalence of rectal signs may be underestimated for two reasons. It was not possible in the EMR to distinguish between patients who had physical examinations with no findings and those who declined part of the physical examination. Because the Center does not perform anoscopy exams routinely in the sexual health clinic, only external rectal signs were detected. In addition, the proportion of treatment visits in which no infection was detected is likely overestimated because urethritis can also be caused by

bacterial or viral agents not routinely tested for at the Center. Routine testing was not performed for *Mycoplasma*, *Ureaplasma*, or *Neisseria meningitidis*. Reviews suggest *M. genitalium* accounts for 10%–25% of non-gonococcal urethritis (NGU) among men, and other causes of NGU among MSM include *Ureaplasma urealyticum*, *Escherichia coli*, oropharyngeal bacteria, herpes simplex virus, and adenoviruses.^{14,15} One gram of azithromycin is the recommended treatment for both *Ureaplasma* and *M. genitalium*; however, *M. genitalium* has shown increasing resistance to azithromycin, so presumptive gonorrhea treatment may be inadequate to clear all infections.^{16,17}

Although significant differences in presumptive treatment by sexual orientation were not observed in bivariate associations, it is possible that grouping together gay, bisexual, and other MSM for the other analyses limits the ability to detect potential differences between these populations.

The gonorrhea positivity among patients treated presumptively was lower than that observed in the small studies of MSM^{9,10} and higher compared with larger studies of presumptive treatment in U.S. emergency departments, in which gonorrhea positivity was consistently <15%.^{18,19} Although, as this study demonstrates, overtreatment in settings with high gonorrhea prevalence is likely to be lower than in general clinical settings, there is still room for improvement. Overtreatment of uninfected individuals may have several deleterious effects, including side effects, possible increased risk of *Clostridium difficile* infection, and the potential to promote antimicrobial resistance of other species of bacteria colonizing the site of infection.^{20,21} Presumptive treatment is unlikely to lead to antibiotic resistance in individuals who receive presumptive treatment only once. However, in individuals who receive multiple courses of presumptive treatment, it is plausible that endogenous bacteria could acquire resistance that is then passed on to subsequent colonization by *Neisseria gonorrhoeae*. This relationship is speculative as no previous studies to our knowledge have examined the link between presumptive treatment and antimicrobial resistance.

Further studies should examine presumptive treatment in other populations with high incidence of gonorrhea, as well as how the precision and accuracy of presumptive treatment may be improved among MSM. The predictive values of specific gonorrhea symptoms, particularly urethral discharge, and whether anoscopy examinations improve identification of rectal gonorrhea, also warrant further investigation. Since anoscopy is often uncomfortable or painful—particularly for patients with rectal inflammation—any diagnostic improvement would need to be weighed against the burden to patients. Currently, the World Health Organization (WHO) provides an algorithm for syndromic management of urethral gonorrhea in men for use in resource-limited settings.²² Similar tools are not available for extragenital gonorrhea, nor does the WHO algorithm include self-reported symptoms. Policies that include empiric extragenital treatment recommendations are needed to improve management of gonorrhea for MSM.

Conclusion

There are opportunities to improve presumptive treatment of gonorrhea in clinics serving populations with a high burden

of disease. Challenges related to asymptomatic infections and nonspecific symptoms and concerns about antibiotic resistance remain. Opportunities for improving presumptive treatment include implementing point-of-care testing for extragenital sites, modifying syndromic management algorithms to accommodate rectal and pharyngeal gonorrhea, as well as self-reported genitourinary symptoms, and establishing prevalence of other etiologic agents.

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