Published in final edited form as:

Sex Transm Dis. 2015 May ; 42(5): 233–239. doi:10.1097/OLQ.0000000000000248.

***Neisseria gonorrhoeae* and *Chlamydia trachomatis* among Women Reporting Extragenital Exposures**

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Abstract

Introduction—The CDC recommends pharyngeal screening of *Neisseria gonorrhoeae* (GC) and rectal screening of GC and *Chlamydia trachomatis* (CT) in HIV-infected and at-risk men who have sex with men (MSM). There are currently no recommendations to routinely screen women at extragenital sites. We define the prevalence of extragenital GC and CT in women attending two urban STD clinics in Baltimore City and compare it to the prevalence of extragenital infections in MSM and men who have sex with women (MSW).

Methods—All patients who reported extragenital exposures in the preceding 3 months, who presented for care between 6/1/2011 and 5/31/2013, and were tested for GC and CT using nucleic acid amplification tests at all sites of exposure were included in the analyses. We used logistic regression models to identify risk factors for extragenital infections.

Results—10,389 patients were included in this analysis (88% African American, mean age 29 years, 42% women, 7% MSM, 2.5% HIV infected). The prevalence estimates of any extragenital GC and CT were: 2.4% GC and 3.7% CT in women; 2.6% GC and 1.6% CT in MSW; 18.9% GC and 11.8% CT in MSM. Among women, 30.3% of GC infections and 13.8% of CT infections would have been missed with urogenital-only testing. Unlike MSM, age 18 years was the strongest predictor of extragenital infections in women.

Conclusions—Although the prevalence of extragenital gonorrhea and chlamydia is highest in MSM, a significant number of GC and CT infections in young women would be missed with genital-only testing. Cost-effectiveness analyses are needed to help inform national guidelines on extragenital screening in young women.

Background

Recommendations from the CDC only call for pharyngeal screening of *Neisseria gonorrhoeae* (GC) and rectal screening of GC and *Chlamydia trachomatis* (CT) in HIV-

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Conflicts of Interest: None for all authors

Portions of data from this manuscript were presented as posters at the American College of Physicians Meeting in Orlando, FL (April 10–12, 2014) and the CDC STD Prevention Conference meeting in Atlanta, GA (June 9–12, 2014).

infected and at-risk MSM.¹ There are no routine recommendations for the extragenital screening of women. The prevalence of extragenital STIs in some women may be significant.^{2,3,4,5,6} Untreated pharyngeal GC, although generally asymptomatic,⁷ can be passed to sexual partners through oral sex.⁸ It has also been shown that the pharynx may be the site of resistance acquisition.⁹ Rectal GC and CT can present with discharge and proctitis, but are usually asymptomatic.^{10,11}

Our aim was to examine the prevalence of extragenital GC and CT in women reporting extragenital exposures and to compare these rates to those observed in MSM and men who have sex with women (MSW) among patients accessing care at two public STD clinics in Baltimore, MD. We determined the proportion of infections that would have been missed had only urogenital testing been performed, the number of persons needed to test to diagnose a case of extragenital CT or GC, and the predictors of extragenital infections.

Methods

This was a retrospective study from an electronic database. All patients who reported extragenital exposures in the preceding 3 months, who presented for care between 6/1/2011 and 5/31/2013, and were tested for GC and CT using nucleic acid amplification tests at all sites of exposure were included in the analyses. Our clinics implemented extragenital screening for all patients who reported extragenital exposures to determine the prevalence of extragenital infections in our population and to inform the approach that the clinic would adopt for future extragenital testing. This analysis was granted approval by the institutional review board of the Johns Hopkins Medical Institutions.

Information on patients that visit either the Baltimore City Health Department Eastern Health District or the Druid Health Center is collected in an electronic patient database. Both clinical and laboratory data were recorded in this study. The clinical assessment includes a structured interview on current symptoms, STI history and behavioral risk factors, a physical examination, clinician impressions, treatment, and referrals. Patients are asked about the reason for their visit [e.g. routine checkup, contact with an infected partner, current symptoms (which included pharyngitis, urogenital discharge, dysuria, genital lesion, genital itching, rash, and irritation/odor, rectal pain, and rectal discharge)], sexual exposures (genital, oral, rectal), illicit drug use, number of sexual partners, prior STI history, sexual orientation and sexual risk behaviors. Rectal exposure was defined as mouth to rectum, penis to rectum, or rectal exposure through shared sex toys. A directed physical examination on each patient includes evaluation of the oropharynx, skin, abdomen, genitals, and when indicated, rectum. This examination documents abnormalities such as rashes, discharge and ulcers. All findings on the history, physical examination and outside referrals are documented on the encounter form and captured in the electronic clinical database. Laboratory data were also recorded in the database.

Extragenital gonorrhea and chlamydia were diagnosed via NAAT performed on-site at the Baltimore City Health Department laboratory using the Gen-Probe APTIMA Combo 2 Assay (Gen-Probe Inc., San Diego CA), a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection and differentiation of ribosomal

RNA from CT and GC using the TIGRIS® DTS® analyzer. This assay was used to detect extragenital GC and CT following in-house validation using appropriate positive and negative controls. Genital gonorrhea was diagnosed by culture and confirmed using biochemical testing (Gonocheck-II, TCS Biosciences, United Kingdom) in both men and women. In women, genital chlamydia was diagnosed by NAAT using a clinician-collected endocervical swab and the Gen-Probe APTIMA Combo 2 assay. Due to budgetary constraints, men were not tested for genital CT. They were diagnosed with non-gonococcal urethritis (NGU) based on Gram's stain of urethral secretions demonstrating ≥ 5 WBC per oil immersion field and a negative urethral GC culture¹. The policy at the Baltimore City Health Department has been to screen men for NGU and to limit genital chlamydia NAATs to women. Although we do not have an accurate prevalence of genital CT in men, their extragenital CT results are provided to serve as a comparison.

We compared proportions using the χ^2 test and mean values using the t-test. We calculated a number needed to test (NNT) to detect an isolated extragenital infection. We defined the NNT as 1 divided by the absolute risk reduction. Logistic regression models were used to determine predictors of extragenital infections. Variables that were assessed in the univariate models included race, age, signs and symptoms (abdominal pain, genital discharge, dysuria, genital lesion, genital itching, genital odor, oral lesion, rash, rectal lesion, rectal discharge, or no symptoms), HIV status, use of oral medications for erectile dysfunction in men, use of alcohol, cocaine, heroin, or methamphetamines, needle sharing, sex for alcohol or drugs, history of intravenous drug use, sex with an HIV infected partner, sex with MSM, history of sexual assault and self-reported condom use during the last sexual exposure. Variables that were significant at the $p=0.20$ value in the univariate regression and any biologically relevant variables were included in the multivariable models. Point estimates of odds ratios (OR) with 95% confidence intervals (CI) are presented. Two-tailed p -values less than 0.05 were assumed to represent statistical significance. Data were analyzed using STATA 12.1 (STATA Corporation, College Station, TX).

Results

There were 10,389 patients who were tested for extragenital GC and CT after reporting extragenital exposures. Their demographic, behavioral, and clinical characteristics are summarized in Table 1. Prevalence of gonorrhea and chlamydia among the different populations (women, MSM, and MSW) are also summarized in Table 1. The Venn diagram demonstrates the relationship between prevalence of extragenital and genital GC and CT infections among women (Figure 1). Of those who reported extragenital exposures, 30.3% (95% CI: 23.4–37.9) of all cases of GC and 13.8% (95% CI: 10.7–17.6) of all cases of CT would have been missed had extragenital testing not been performed. Eighty three women (95% CI: 63–112) would have to be tested to detect an isolated extragenital GC infection. In comparison, 8 MSM (95% CI: 6–10) and 67 MSW (95% CI: 53–88) would have to be tested to detect an isolated extragenital GC case. Similarly, 60 women (95% CI: 47–80) would have to be tested to detect an isolated extragenital CT infection. In comparison, 10 MSM (95% CI: 8–13) and 75 MSW (95% CI: 58–98) would have to be tested to detect an isolated extragenital CT case. If we were to exclude all symptomatic patients and patients who were known contacts to a confirmed case of GC and CT, 43 women (95% CI: 31–60), 6 MSM

(95% CI: 5- 8) and 69 MSW (95% CI: 50–99) would have to be tested to detect an isolated extragenital GC case. Similarly, 24 women (95% CI: 19- 31), 10 MSM (95% CI: 7- 13) and 58 MSW (95% CI: 43–82) would have to be tested to detect an isolated extragenital CT case.

In the multivariable models (Table 2), age ≥ 18 years was the strongest predictor of any extragenital infections in women. Age <18 years was significantly associated with isolated GC of the throat and CT of the rectum. No factors were significantly associated with isolated GC of the rectum and CT of the throat. IV drug use was only associated with an increased risk of any pharyngeal GC. White women had a higher odds of being diagnosed with any pharyngeal CT compared to African American women. No other variables, including clinical signs and symptoms, were significantly associated with extragenital infections in women. Age ≥ 18 years was associated with increased odds of pharyngeal GC [aOR 3.3; 95%CI: 1.6–7.0] and CT [aOR 7.7; 95%CI: 2.9–20.3] among MSW but not MSM. When we assessed predictors of isolated extragenital infections, age <18 years was a significant predictor of throat GC and rectal CT (Table 2) but was no longer a significant predictor of GC of the rectum (aOR 4.7, 95% CI: 0.3–77.2) and CT of the throat aOR 1.5 (95%CI: 0.5–4.3).

Discussion

Most guidelines that address extragenital testing for GC and CT have focused on MSM^{1,12} given the burden of these infections in that population.¹³ Among MSM who reported extragenital sexual exposures in our clinics, the prevalence of GC and CT was three to eight-fold higher than in women. The prevalence of extragenital infections in women, however, was not insignificant. The prevalence of rectal GC was higher than genital GC and 30% of GC infections in women would have been missed with a genital-only testing approach. The prevalence of rectal CT was equivalent to genital CT, and about 15% of CT infections would have been missed if extragenital testing were not done. Our findings reflect those of other studies, summarized in Table 3, that have assessed extragenital testing in women. Most studies suggest that 20–40% of GC infections and 10–25% of CT infections in women would be missed if extragenital sites were not tested. Very few MSW reported any anal exposures but MSW had higher rates of pharyngeal GC than women. Their rates of pharyngeal CT were slightly lower.

The absolute burden of extragenital GC and CT infections is significantly different between MSM and women. This is best characterized by comparing the number of patients needed to test to diagnose a single extragenital infection: 6–10-fold more women would need to be tested compared to MSM to diagnose a single extragenital infection in our population. A recent study suggested that extragenital screening for GC and CT may be cost-effective among MSM in high-prevalence settings- depending on the impact of rectal CT/GC screening on HIV incidence.¹⁴ Whether extragenital screening can be cost-effective in women is not known. Extragenital infections can be transmitted to male partners¹⁵ but trying to prevent urethritis in heterosexual men by screening for extragenital infections in their female partners may not make as compelling an argument given the lower risk of HIV acquisition among heterosexuals. Another argument is that screening for extragenital CT in

women may impact chlamydia control on a population level (by preventing infections in male partners who may infect their other female partners), but the ability to measure the impact of this to inform cost-effectiveness studies is challenging. For GC, there is the theoretical risk of the throat being the site of resistance acquisition, but how that would figure into a cost-effectiveness analysis is also unclear. Indeed, the area of cost-effectiveness of extragenital testing in women represents a challenge that has yet to be fully explored.

Young age was the single most important predictor of any extragenital infections in women. Women who were younger than or equal to 18 years had nearly a four-fold increased odds of being diagnosed with an extragenital infection compared to older women. A similar finding was noted among MSW. Hunte et al. found that young age (defined as less than 28 years) was the only risk factor noted to be associated with extragenital infections among women attending an STD clinic in Miami.² Among MSM, though, the association with young age was less pronounced: age had no impact on the detection of pharyngeal GC and CT whereas older MSM (ages 19–30 years) had a two-fold higher odds of being diagnosed with rectal GC and CT. When assessing women with isolated extragenital infections, young age no longer predicted GC infection of the rectum and CT of the throat. Although both estimated odds ratios suggested a positive association with younger age, the confidence limits were broad either suggesting a lack of association with young age, or limited power due to a significantly reduced sample size.

This study has several limitations. Culture was used to diagnose genital gonococcal infections in both men and women. Given that culture has a lower sensitivity than NAAT, we may have overestimated the number of missed infections with a genital-only testing approach. Our estimates however are in-line with several other sources (Table 3). Testing of extragenital sites was based on sexual history-only those who reported extragenital exposures were tested and testing occurred at the site of reported exposure. Guidelines have, in general, favored testing based on exposure history¹. Whether the prevalence of extragenital infections among women in our clinics who did not report symptoms or exposure is different than those who did is not known. NAAT are not 100% specific, so false positive results cannot be excluded. Rectal infections may reflect cross-contamination from genital secretions. Finally, none of the NAAT are FDA-cleared for extragenital testing. They are, however, considered the tests of choice for detecting extragenital GC and CT infections¹ and a careful in-house validation protocol was conducted to ensure optimal performance.

Although the prevalence of extragenital gonorrhea and chlamydia is highest in MSM, a significant number of gonorrhea and chlamydia cases in women would be missed with genital-only testing. Cost-effectiveness analyses are needed to help inform national guidelines on extragenital screening in young women.

Acknowledgments

Source of Funding: None for all authors

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Summary

In this STD clinic population of women who report extragenital exposures, 30.3% of gonorrhea and 13.8% chlamydia infections would have been missed if extragenital testing were not done.

Figure 1. Genital and extragenital GC (top) and CT (bottom) in women
 GC= *Neisseria gonorrhoeae*; CT- *Chlamydia trachomatis*; CI= confidence intervals

Table 1

Demographic and clinical characteristics of the study population

Total	Overall (N = 10,389)	Women (N=4402)	MSM (N=769)	MSW (N=5218)
Race [%]				
Black	88	88	79*	89 [‡]
White	8	8	15*	6 [‡]
Hispanic	3	2	4*	3
Other	2	2	2	2 [‡]
Age [%]				
<18	7	10	7*	5 [‡]
19–30	60	63	66	57 [‡]
>30	32	27	27	38 [‡]
Sex Orientation [%]				
Opposite Sex only	85	85	0	100
Same Sex	7	5	73	0
Both	5	8	27	0
Unknown	2	2	0	0
Dysuria [%]	10	6	9*	15 [‡]
Discharge [%]	24	33	15*	18 [‡]
Pharyngeal symptoms/signs[%]	0.6	0.6	1.0	0.4
Rectal symptoms/signs [%]	0.7	0.6	3.8*	0.3 [‡]
HIV [%]	2.5	1.0	17.4*	0.7
Mean number of sex partners in preceding 3 months	1.92	1.81	2.15	1.99
Alcohol use at last sex [%]	19.79	15.88	18.99*	23.21 [‡]
IV drug use in past 3 months [%]	0.39	0.70	0.26	0.15 [‡]
Always using a condom during sex [%]	11.58	11.00	20.93*	10.70
GC Genital [%] 95% CI N	3.93 3.56–4.33 (397/10,100)	2.75 2.28–3.29 (116/4222)	8.94* 6.95–11.27 (64/716)	4.27 [‡] 3.73–4.86 (215/5036)
GC Throat [%] 95% CI N	3.01 2.68–3.36 (302/10,044)	2.09 1.68–2.57 (88/4203)	10.97* 8.74–13.53 (76/693)	2.54 2.13–3.02 (128/5032)
GC Rectum [%] 95% CI N	9.79 8.18–11.59 (120/1226)	2.95 1.76–4.62 (18/611)	17.92* 14.71–21.49 (93/519)	5.71 0.70–19.16 (2/35)
CT Genital/NGU** [%] 95% CI N	N/A	9.96 9.04–10.94 (389/3905)	1.46* 1.51–3.98 (18/710)	2.33 1.93–2.79 (118/5060) [‡]

Total	Overall (N = 10,389)	Women (N=4402)	MSM (N=769)	MSW (N=5218)
CT Throat [%]	2.05	2.59	2.45*	1.56
95% CI	1.77–2.37	2.10–3.16	1.38–4.01	1.22–1.96
N	(181/8826)	(95/3662)	(15/612)	(71/4552) [‡]
CT Rectum [%]	11.21	8.64	14.34*	9.09
95% CI	9.44–13.17	6.52–11.17	11.43–17.67	1.91–24.33
N	(129/1151)	(52/602)	(74/516)	(3/33)

GC=*Neisseria gonorrhoeae*; CT= *Chlamydia trachomatis*; NGU= non-gonococcal urethritis; CI= confidence interval; N/A= not applicable; N= number of patients

The difference in denominators between GC and CT reflect a difference in the number of genital tests obtained for GC and CT

* P<0.05 comparing women and MSM

[‡] P<0.05 comparing women and MSW

** Genital CT in women was diagnosed using nucleic acid amplification testing; in men non-gonococcal urethritis was diagnosed by Gram stain criteria (see Methods).

Table 2

Multivariable predictors of (a) any extragenital gonorrhea or chlamydia infection and (b) isolated extragenital gonorrhea and chlamydia infections among women in our cohort.

Site of Infection	Any Extragenital Infection aOR (95% CI)	Isolated Extragenital Infection aOR (95% CI)
GC Throat	-Age < 18 years vs. >30: 3.79 (1.84–7.82)	-Age < 18 years vs. >30: 2.50 (1.02–6.13)
	-White vs. Black: 2.20 (1.19–4.06)	White vs. Black: 3.23 (1.52–6.90)
	-IVDU: 5.44 (1.49–19.86)	IVDU: 7.72 (2.04–29.21)
GC Rectum	-Age 18–30 years vs. >30: 5.03 (1.13–22.28)	NS
CT Throat	-Age < 18 years vs. >30: 3.74 (1.78–7.86)	NS
	-Age 18–30 years vs. >30: 2.13 (1.14–3.98)	
CT Rectum	-Age < 18 years vs. >30: 23.57 (7.23–76.75)	Age < 18 years vs. >30: 11.69 (2.13–64.04)
	-Age 18–30 years vs. >30: 5.52 (1.92–15.86)	

GC= gonorrhea; CT= Chlamydia trachomatis; aOR= adjusted odds ratio; CI= confidence interval; IVDU= intravenous drug use in the past 3 months; NS= not significant

GC throat models included variables for race, age, sexual orientation, and Intravenous drug use.

GC rectal models included variables for age, race, and sexual orientation

CT throat models included variables for age, race, and sexual orientation.

CT rectal models included variables for age, race, and sexual orientation

Table 3
A summary of studies that assessed prevalence of extragenital gonorrhea and chlamydia in women

Study First Author	Year	Population/Setting	GC Prevalence Throat (95% CI)	GC Prevalence Rectum (95% CI)	CT Prevalence Throat (95% CI)	CT Prevalence Rectum (95% CI)	% missed CT and GC (95% CI)
Trebach JD, et al. (current study)	2014	Baltimore City Health Department Eastern Health District and Druid Health Center, Maryland	2.09 (1.68–2.57) N=4203	2.95 (1.76–4.62) N=611	2.59 (2.10–3.16) N=3662	8.64 (6.52–11.17) N=602	CT: 13.8% (10.7–17.6) GC: 30.3% (23.4–37.9)
Van Liere, G et al. ¹⁶	2014	South Limburg Public Health Service STI clinic, Netherlands	2.3% (1.54–3.23) N=1321	0.9% (0.47–1.58) N=1321	1.4% (0.87–2.23) N=1321	4.8% (3.68–6.06) N=1321	CT: 22.8% (14.72–32.75) GC: 58.5 (42.11–73.68)
Garner AL, et al. ⁴	2014	Manchester Centre for Sexual Health, UK	0.6% (0.17–1.59) N=642	1.1% (0.03–5.97) N=91	2.5% (1.43–4.02) N=642	6.6% (2.46–13.80) N=91	CT: 12.9% (5.74–23.85) GC: 28.5% (3.67–70.96)
Ladd J, et al. ¹⁷	2014	Home testing using iwanthekit.org	N/A	2.4% (0.80–5.60) N=205	N/A	12.7% (8.45–18.03) N=205	N/A
Jenkins WD, et al. ³⁰	2014	Memorial Medical Center Emergency Department, IL	0.66% (0.18–2.38) N=301	N/A	0.66% (0.18–2.38) N=301	N/A	Pharyngeal CT: 0% Pharyngeal GC: 9.09% (2.53–27.81)
Shaw SG, et al. ¹⁸	2013	STI center in the United Kingdom	0.28% (0.03–0.49) N=1799	0.64% (0.08–2.30) N=312	1.3% (0.81–1.91) N=1799	7.1% (4.47–10.48) N=312	N/A
Koedijk FDH, et al. ⁵	2012	STI centers in the Netherlands	1.20% (1.15–1.25) N = 206,513	1.20% (1.15–1.25) N = 207,134	2.70% (2.63–2.77) N = 206,720	9.3% (9.18–9.43) N = 206,720	CT: 12.9% (N/A) GC: 30.0% (N/A)
Javanbakht M, et al. ⁶	2012	STD clinics in Los Angeles County, CA	N/A	3.0% (2.27–3.80) N=2026	N/A	14.6% (12.29–16.32) N=1203	CT: 25% (19.41–32.14) GC: 18.5% (10.75–28.70)
Rodriguez-Hart C, et al. ³	2012	Adult film performers	22.32% (15.00–31.16) N=112	16.96% (10.53–25.22) N=112	N/A	3.57% (0.98–8.89) N=112	CT & GC: 15% (N/A)
Karlsson A, et al. ¹⁹	2011	Porsö Health Care Centre and Gällivare Centre for Young Persons, Sweden	N/A	N/A	12% (6.12–20.39) N=92	N/A	N/A
Peters RP, et al. ²⁰	2011	STD Clinic-The Hague	0.8% (0.54–1.14) N = 3750	1.7% (0.96–2.81) N = 876	1.9% (1.48–2.38) N = 3750	8.7% (6.90–10.74) N = 876	N/A

Study First Author	Year	Population/Setting	GC Prevalence Throat (95% CI)	GC Prevalence Rectum (95% CI)	CT Prevalence Throat (95% CI)	CT Prevalence Rectum (95% CI)	% missed CT and GC (95% CI)
Bachmann LH, et al. ²¹	2010	Clinics in AL and IL	N/A	16.46% (9.88–26.15) N=79	N/A	32.14% (23.12–42.72) N=84	Rectal CT: 23.33% (11.79–40.92) Rectal GC: 15.79% (5.52–37.57)
Tipple C, et al. ²²	2010	UK STI Center	N/A	N/A	1.9% (1.05–3.05) N=805	N/A	N/A
Giannini CM, et al. ²³	2010	Adolescent hospital STD Clinic (adolescents) STD Clinic (Adults)	3.5% (1.0–6.2) N=195; 6.8% (3.8–9.9) N=263; 2.5% (1.4–3.5) N=887	2.9% (0.1–5.7) N=140; 13.4% (3.9–23) N=52; 5.2% (2.7–7.7) N=308	N/A	N/A	Adolescents GC: 14–26% (N/A) Adolescents (hospitalized): 11% (N/A) Adults GC: 20–40% (N/A)
Hunte T, et al. ²	2010	Miami Dade Health Department STD Clinic	N/A	13.4% (7.33–21.83) N=97	N/A	17.5% (10.55–26.57) N=97	Rectal CT: 6% (0.15–28.69) Rectal GC: 38% (13.86–68.42)
Barry PM, et al. ²⁴	2010	San Francisco STD Clinic	N/A	1.7% (1.06–2.54) N=1308	N/A	4.7% (3.65–6.03) N=1308	Rectal GC: 0.1% (0.0–0.43) Rectal CT: 1.0% (0.53–1.69)
Raychaudhuri M, et al. ²⁵	2010	STI clinic; UK	N/A	35.83% (27.29–45.10) N=120	N/A	N/A	GC 5.8% (2.38–11.65)
Van der Helm JJ, et al. ²⁶	2009	Clients of Amsterdam and South Limburg STI outpatient centers	N/A	1.9% (1.1–3.2) N=697	N/A	9.4% (7.7–11.5) N=901	N/A
Bachmann LH, et al. ²⁷	2009	Public STD clinic, HIV clinic, university-based HIV clinic; Alabama.	9.1% (6.18–13.17) N=264	N/A	N/A	N/A	N/A
Ostergaard L, et al. ²⁸	1997	Rudolph Bergh Hospital, Denmark	N/A	N/A	1.53% (0.52–4.40) 3/196	5.61% (3.16–9.77) 11/196	CT: 13.04% (4.54–32.12)
Jones RB, et al. ²⁹	1985	Indiana STD clinics	N/A	N/A	3.2% (1.96–4.89) N=626	5.2% (4.04–6.61) N=1227	N/A

GC= *Neisseria gonorrhoeae*; CT=*Chlamydia trachomatis*; CI= confidence interval; N/A= not available or cannot be calculated;

Unless otherwise indicated, implies both rectal and pharyngeal.