Test-of-Cure After Treatment of Pharyngeal Gonorrhea in Durham, North Carolina, 2021–2022

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Background: In December 2020, the Centers for Disease Control and Prevention updated its treatment guidelines for gonococcal infection and, for the first time, recommended universal test-of-cure for all individuals treated for pharyngeal gonorrhea. After the release of these guidelines, data are lacking on rates of return for the test-of-cure, particularly in populations other than men who have sex with men.

Methods: We analyzed the demographic characteristics, clinical characteristics, rate of return for the recommended test-of-cure, and percent positivity for *Neisseria gonorrhoeae* on repeat pharyngeal specimens at a local public health department in Durham, NC.

Results: Of 101 individuals treated for pharyngeal gonorrhea between March 2021 and April 2022, 54.5% were men, 71.2% Black or African American, and 58.4% between the ages of 20 and 29 years. Most identified as either women who have sex with men (38.6%), men who have sex with men (24.8%), or men who have sex with women (22.8%). Of these individuals, 41 (40.6%) returned for a test-of-cure, with LGBTQ+ individuals more likely to return than men who have sex with women and women who have sex with men. Of those who returned for the test-of-cure, 4.9% of pharyngeal samples were equivocal and 2.4% positive for *N. gonorrhoeae* by nucleic acid amplification testing, likely reflecting false-positive tests.

Conclusion: Despite recommendations to perform a test-of-cure 7 to 14 days after treatment of pharyngeal gonorrhea, rates of return continue to be low. Alternative strategies should be investigated to increase test-of-cure rates.

With rates of gonorrhea (GC) infection caused by the bacteria *N. gonorrhoeae* increased by 92% in the United States over a 10-year period from a historic low in 2009[1] and the increasing threat posed by antibiotic-resistant GC strains, there is increased focus on mainstay public health measures to control GC infection: prevention, screening, case finding, and treatment. In men, GC urethritis is typically symptomatic, whereas extragenital infection is asymptomatic, and most women have no symptoms of GC infection,[2,3] identifying those with GC can be challenging. Furthermore, as testing for chlamydia (CT) and GC at extragenital sites has become a more common practice, detection of pharyngeal and rectal GC is increasing. In 1 study of men who have sex with men (MSM) attending Sexual Health clinics in San Francisco, California, almost 7% and 10% of men had rectal and pharyngeal GC diagnosed, respectively, of which the vast majority were asymptomatic. In addition, up to 30% had concomitant CT infection diagnosed, with prevalence varying by the site tested.[4] Although there are less data on the prevalence of extragenital GC in women, asymptomatic rectal and oral GC has been noted in women reporting recent receptive anal and oral sex.[5,6]

Although extragenital GC rarely causes significant morbidity, it does serve as a reservoir for transmission, and both rectal GC and CT increase the risk of human immunodeficiency virus (HIV) acquisition, a risk independent of sexual behavior.[7] One challenge is that *N. gonorrhoeae* in the pharynx may be more difficult to eradicate than at other sites, possibly because of variable drug concentrations in the pharyngeal tissue, requiring longer intervals of drug concentration above the strain's minimum inhibitory concentration (MIC) to be therapeutic.[8,9] As a result, infection at this site has been associated with higher rates of treatment failures.[10] Although European and Canadian guideline groups have recommended routine test-of-cure (TOC) in all persons with GC infection,[11–13] this practice in the United States has historically been controversial and reserved for persons with pharyngeal GC treated with regimens other than first-line treatment.[14] In December of 2020, the Centers for Disease Control and Prevention (CDC) recommended increasing the dose of ceftriaxone from 250 mg to 500 mg (for individuals weighing less than 150 kg) and 1000 mg (for individuals weighing greater than 150 kg) and, for the first time, recommended universal TOC using culture or nucleic acid amplification tests (NAATs) 7 to 14 days after initial treatment for persons treated for pharyngeal GC, regardless of treatment regimen used.[15]

Data on the rate of return for TOC after treatment for GC infection vary. In studies of MSM with urethral and extragenital GC seen at Sexual Health clinics in large urban areas in the United States, rates of return for TOC vary between 26.3% at 7 days and 44.2% between 7 and 30 days, with 5.3% to 10% of pharyngeal specimens collected at these TOC visits positive for *N. gonorrhoeae* by NAAT.[16,17] In another study of individuals seen at Sexual Health clinics with pharyngeal GC, of which 83.4% were MSM, 6.0% were men who have sex with women (MSW), and 7.3% were women who have sex with men (WSM), the rate of return for TOC was 8.5% within 30 days of treatment, with 4.3% of pharyngeal specimens positive for *N. gonorrhoeae* by NAAT at these follow-up visits.[18]

Since the CDC issued these revised recommendations in December 2020, data are lacking on rates of return for the TOC, particularly in non-MSM populations. We investigated the demographic characteristics of individuals diagnosed with pharyngal GC at the Sexual Health Clinic in the Durham County Department of Public Health, located in the Southern United States in a county with a population of 326,000.[19] We also analyzed rates of concomitant diagnosis of CT and syphilis infection, assessed the rate of return for the recommended TOC, and percent of repeat pharyngeal specimens positive for *N. gonorrhoeae.*

MATERIALS AND METHODS

We reviewed the electronic health records (Epic, Verona, WI) from March 1, 2021, to April 30, 2022, of individuals seen

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in our Sexual Health Clinic at the Durham County Department of Public Health in Durham, NC, who were diagnosed with pharyngeal GC. In our Sexual Health Clinic, we routinely test all individuals for pharyngeal GC and CT who engage in oral sex, are a sexual contact to someone diagnosed with GC or CT, or have pharyngeal symptoms. A diagnosis of pharyngeal GC was made based on a positive transcription-mediated amplification test for *N. gonorrhoeae* and *C. trachomatis* using the APTIMA Unisex Swab Collection Kit (Hologic, San Diego, CA) at the Durham County Department of Public Health laboratory. A list of individuals with a positive NAAT for *N. gonorrhoeae* was given to the study investigators. For those individuals seen in the Sexual Health Clinic at the Durham County Department of Public Health, demographic, clinical, and treatment data were collected through review of their electronic health record (EHR). The laboratory at the Durham County Department of Public Health analyzes specimens via NAAT for *C. trachomatis* and *N. gonorrhoeae* sent from outside the Sexual Health Clinic, primarily from our outreach teams who perform sexually transmitted infection (STI) testing in the community. Because information on these individuals was not available for further review, these individuals were considered unevaluable and were excluded from this study.

We reviewed demographic, clinical, treatment data, and rates of return for the TOC visit for all evaluable individuals. Age was divided into 4 groups (<20 years, 20–29 years, 30–39 years, and >40 years). Sex was self-reported and defined as male, female, transgender, or nonbinary. Race/ethnicity was self-reported and defined as white/non-Hispanic, Black or African American/non-Hispanic, Asian/non-Hispanic, Hispanic, American Indian and Alaska Native, or unknown/not disclosed. Human immunodeficiency virus infection status was based on HIV test results documented in the EHR and defined as negative, positive, or unknown. Preexposure prophylaxis (PrEP) status was determined based on the client's self-report of taking either tenofovir disoproxil fumarate and emtricitabine (Truvada) or tenofovir alafenamide and emtricitabine (Descovy) or documentation in the EHR. Sexual orientation was either self-reported or determined by the treating clinician based on reported sex partners and categorized as MSW, WSM, MSM, women who have sex with women (WSW), men who have sex with men and women (MSM&W), women who have sex with men and women (WSM&W), nonbinary individuals who have sex with men and women (NSM&W), and unknown.

Symptom assessment was based on the presence or absence of urethral or anorectal symptoms, including genital/rectal lesions, vaginal discharge, increased urinary frequency, burning with urination, penile discharge, rectal pain, and rectal discharge. Pharyngeal symptoms were based on the presence or absence of a sore throat or pharyngeal lesions. If an individual was diagnosed with either *C. trachomatis* or syphilis infection at the same visit, this was considered a concomitant diagnosis. Treatment was categorized based on the type of antibiotic given and included CDC recommended therapies including ceftriaxone 500 or 1000 mg intramuscular (IM) given once (weight-based), cefixime 800 mg oral given once (for individuals who declined the ceftriaxone injection), or gentamicin 240 mg IM given once plus azithromycin 200 mg oral given once (for individuals with a severe penicillin allergy).

Test-of-cure was routinely offered to individuals diagnosed with pharyngeal GC during the study period and occurred if an individual return to the sexual health clinic for reassessment and a repeat pharyngeal test for *N. gonorrhoeae* by NAAT. If an individual returned for a TOC within 30 days from treatment, we assessed the duration in days from treatment date that the TOC was done (<7 days, 7–11 days, 12–14 days, or >14 days), and whether the repeat pharyngeal test was positive for *N. gonorrhoeae.* If no TOC was done, we assessed the reason why, which included reasons such as the client was not scheduled for a TOC, was scheduled for a TOC but canceled or failed to show up for the appointment, did not respond to follow-up phone calls or letters to schedule the TOC, or was unable to follow-up (had moved and left the area). If the repeat pharyngeal test was positive for *N. gonorrhoeae* by NAAT, a culture was performed as well.

We performed χ^2 and Fisher exact test using SAS 9.4. χ^2 Test was used when categories had a sample size of greater than 5 (urethral/anorectal GC symptoms, a concomitant CT diagnosis, and concomitant Syphilis diagnosis, days after treatment), whereas Fisher exact test was used when categories had a sample size of less than or equal to 5. The statistically significant difference among sexual orientation and return for TOC was examined further. Individuals were grouped into 2 categories, LGBTQ+ (MSM&W, WSM&W, WSW, MSM, and NSM&W) and heterosexual (MSW, WSM). Individuals with unknown sexual orientation were excluded from this analysis (n = 96). The odds ratio was calculated to identify the difference between the 2 categories and their TOC visit status.

This project was exempted as nonresearch by the Durham County Department of Public Health Review Board.

RESULTS

Of 146 EHRs reviewed that had a positive NAAT for *N. gonorrhoeae* from pharyngeal swab during the study period, we included 101 in our analysis. Of those that were unevaluable, 40 EHRs lacked any clinical data associated with the diagnosis of pharyngeal GC, mostly because the GC/CT testing was performed outside of our Clinic; 2 individuals failed to show up for their initial GC treatment so were excluded; 1 EHR was a repeat positive GC test at a TOC visit and, thus, was considered a positive result on TOC; 1 EHR lacked a diagnosis of pharyngeal GC; and 1 EHR included a laboratory test done as a laboratory control and was not a diagnosis of pharyngeal GC on an actual person.

The majority diagnosed with pharyngeal GC were male (n = 55, 54.5%), Black or African American (n = 72, 71.2%), and between the ages of 20 to 29 years (n = 59, 58.4%) (Table 1). Most identified as WSM (n = 39, 38.6%), MSM (n = 25, 24.8%), or MSW (n = 23, 22.8%). The vast majority did not have HIV infection (n = 83, 82.2%) and were not on PrEP (n = 88, 87.1%). Just over half of individuals presented with either genitourinary or anorectal symptoms (n = 53, 52.5%), whereas less than 10% endorsed any pharyngeal symptoms. Twenty persons (20%) were diagnosed with CT and 5 (5%) with syphilis at the time of their clinic visit. The vast majority (n = 93, 95%) were treated with the recommended regimen of intramuscular ceftriaxone.

Those who identified as MSW or WSM were less likely to return for the TOC visit than those who identified as LGBTQ+ (MSM&W, WSM&W, WSW, MSM, and NSM&W) (odds ratio, 0.29; 95% confidence interval, 0.12–0.71; $P = 0.0052$). There was no significant association between age, sex, race/ethnicity, HIV status, PrEP status, symptom status, concomitant CT or syphilis diagnosis, or treatment regimen used and those who returned or did not return for the TOC visit.

Overall, 40.6% (n = 41) of individuals returned for the TOC visit and 59.4% (n = 60) did not (Table 2). Of those who did not return for the TOC visit, the majority either canceled their appointment or failed to show up for the scheduled visit (n = 41, 68.3%). Fifteen percent did not respond to requests to schedule a TOC visit, and 15% were not scheduled for a TOC visit by the treating clinician. Of those who returned for the TOC visit, the vast majority (n = 36, 87.8%) returned within the recommended 7 to 14 days. Of those who returned for the TOC, 38 (92.7%) had a

TABLE 1. Characteristics of Individuals With Treated Pharyngeal GC by TOC Visit Status

			Return for TOC Visit				
	Total, N = 101		No, n = 60		Yes, n = 41		
Characteristics	**n**	**%**	**n**	**%**	**n**	**%**	***P***
Age, y							
<20	9	8.9	5	8.3	4	9.8	0.9470
20–29	59	58.4	34	56.7	25	60.1	
30–39	24	23.8	15	25.0	9	22.0	
>40	9	8.9	6	10.0	3	7.3	
Sex							
Male	55	54.5	30	50.0	25	60.1	0.4563
Female	44	43.6	29	48.3	15	36.6	
Nonbinary	2	2.0	1	1.7	1	2.4	
Transgender	0	0	0	0	0	0	
Race/ethnicity							
Black or AA/NH	72	71.2	42	70.0	30	73.2	0.8257
White/NH	12	11.9	8	13.3	4	9.8	
Hispanic	10	9.9	5	8.3	5	12.2	
AIAN	2	2.0	1	1.7	1	2.4	
Unknown	5	5.0	4	6.7	1	2.4	
Asian/NH	0	0	0	0	0	0	
Sexual orientation							
WSM	39	38.6	25	41.7	14	34.1	***0.0052**
MSM	25	24.8	9	15.0	16	39.0	
MSW	23	22.8	17	28.3	6	14.6	
MSM&W	5	5.0	2	3.3	3	7.3	
WSM&W	3	3.0	2	3.3	1	2.4	
NSM&W	1	1.0	0	0	1	2.4	
Unknown	5	5.0	5	8.3	0	0	
HIV status							
Negative	83	82.2	46	76.7	37	90.2	0.0759
Positive	7	6.9	4	6.7	3	7.3	
Unknown	11	10.9	10	16.7	1	2.4	
On PrEP							
Yes	10	9.9	4	6.7	6	14.6	0.1900
No	88	87.1	53	88.3	35	85.4	
Unknown	3	3.0	3	5.0	0	0	
Urethral/anorectal symptoms							
Symptomatic	53	52.5	32	53.3	21	51.2	0.8424
Asymptomatic	48	47.5	28	46.7	20	48.8	
Pharyngeal symptoms							
Symptomatic	9	8.9	5	8.3	4	9.8	1.0000
Asymptomatic	92	91.1	55	91.2	37	90.2	
Concomitant CT diagnosis							
Yes	20	19.8	13	21.7	7	17.1	0.5694
No	81	80.2	47	78.3	34	83.0	
Concomitant syphilis diagnosis							
Yes	5	5.0	3	5.0	2	4.9	1.0000
No	96	95.0	57	95.0	39	95.1	
Treatment							
CTX	96	95.0	56	93.3	40	97.6	0.7874
CFM	1	1.0	1	1.7	0	0	
GEN + AZM	4	4.0	3	5.0	1	2.4	
Unable to treat	0	0	0	0	0	0	

AA, African American; AIAN, American Indian or Alaskan Native; AZM, azithromycin; CFM, cefixime; CTX, ceftriaxone; GEN, gentamicin; NH, non-Hispanic.
*Significant between MSW and WSM versus LGBTQ+ (MSM&W, WSM&W, WSW, MSM, and NSM&W) using Fisher exact test.

negative repeat NAAT for GC, 2 (4.9%) had an equivocal test, and 1 person (2.4%) had a repeat positive test. Of those with an equivocal TOC, 1 person had a TOC on day 10 after treatment and did not return for repeat testing, and the other had an equivocal TOC on day 7 after treatment and a repeat NAAT on day 15, which was negative. The sole person with a positive TOC had this done on day 7 after treatment with no interval sexual activity. A confirmatory culture was sent for susceptibility testing but the culture was negative, likely reflecting a false-positive NAAT.

DISCUSSION

Before the release of the revised CDC treatment guidelines recommending TOC after the treatment of pharyngeal GC, studies investigating TOC in mostly MSM populations in large urban areas found rates of return ranging from 8.5% to 44.2%.[16–18] Since the CDC issued revised recommendations in December 2020 for routine TOC in all individuals treated for pharyngeal GC,[15] data are lacking on rates of return for the TOC visit, particularly in

TABLE 2. Characteristics of TOC Visits

	n	%
TOC visit completed		
Yes	41	40.6
No	60	59.4
If TOC visit completed, no. days after treatment		
<7	1	2.4
7–11	18	43.9
12–14	18	43.9
>14	4	9.8
If TOC visit not completed, why		
Scheduled but client canceled or did not show	41	68.3
Client did not respond to requests to schedule	9	15.0
Not scheduled	9	15.0
Unable to follow-up	1	1.7
If repeat GC testing performed, was it positive?		
Yes	1	2.4
No	38	92.7
Equivocal	2	4.9

non-MSM populations, including in the Southern United States. Here, we investigate individuals diagnosed with pharyngeal GC at our Sexual Health Clinic in Durham, NC. From March 2021 to April 2022, we found that only 40.6% of individuals returned for the TOC visit, even though over 83% of individuals were either scheduled for TOC, or efforts were made to schedule them. These findings are consistent with findings from studies performed before the release of the revised CDC recommendations.

Our analysis differed from previous studies in that almost half of individuals diagnosed with pharyngeal GC were either WSM or MSW rather than MSM, and the vast majority identified as either Black or African American, reflecting a more diverse patient population in our setting compared with those from other studies. Although the CDC recommends "consideration" for extragenital GC screening in women based on sexual behaviors and exposure,[20] our findings suggest that pharyngeal GC may be rather common in women, including WSM, and that more aggressive screening in women may be indicated. In addition, we investigated TOC outcomes after treatment with the current recommended dose of ceftriaxone, unlike other studies in which the dose of ceftriaxone was 250 mg, consistent with previous guidelines. Lastly, this study occurred in the Southern United States in a largely non-MSM population where there is less published data on this topic.

We found that those who identified as LGBTQ+ were more likely to return for TOC than WSM and MSW, but we did not find any other associations between return for TOC and age, sex, race/ethnicity, HIV status, PrEP status, or symptom status at the time of presentation. This differed from 1 study of MSM in New York City that found a significant association between older than 30 years and persons without HIV infection and a higher rate of return for TOC, and an association between Black/African American race and not returning for TOC.[17] Another study of MSM in Los Angeles, California found a significant association between taking PrEP and lack of symptoms at the time of testing and a higher rate of return for TOC.[16]

Of those who returned for a TOC, 2 (4.9%) had an equivocal test and 1 person (2.4%) had a repeat positive test. Given that the specimens that resulted as equivocal were collected on days 7 and 10 and the positive specimen was collected on day 7 after treatment (which was negative on repeat testing on day 15), it is likely that these tests detected residual RNA from the original infection rather than reinfection and did not reflect true reinfection. Positive results from residual RNA or DNA can lead to excessive and unnecessary antibiotic treatment, as in these cases. We agree with CDC recommendations that testing at 7 days posttreatment may lead to a higher likelihood of false-positive tests, and it may be prudent to perform the TOC 10 to 14 days after treatment to reduce this potential.[15]

Given the low rates of return for TOC in our setting, we suspect that clinicians in other settings are facing similar challenges aligning with the revised guidance from the CDC. Although attempts were made to schedule 83% of individuals treated for pharyngeal GC for TOC, 15% of individuals were not scheduled for various reasons by the treating clinician and improvements need to be made in this process to ensure that everyone is offered an opportunity for TOC. Still, persons diagnosed with pharyngeal GC are by-in-large asymptomatic, and particularly after receiving treatment for GC, may not be strongly motivated to return for a TOC when feeling well and it is inconvenient to do so, even when scheduled. Thus, alternative strategies for TOC should be investigated, such as implementing programs so testing can be done at laboratory-only visits, for example, where an appointment is not required. Another option would be to perform at-home TOC, which would offer an even more convenient testing option. There are numerous for-profit entities that provide at-home STI testing options and some nonprofit entities, including Planned Parenthood[21] and the Alabama Department of Public Health.[22] Home testing would obviate the need for a return visit and may increase TOC rates. Multiple studies have found the sensitivity and specificity of at-home testing to be comparable to in-clinic testing[23,24] and noted that patients find self-collected, at-home testing easier[25] and preferable[26] to in-clinic testing.

Lastly, this study provides a snapshot of PrEP usage in our patient population, at least the subset diagnosed with pharyngeal GC. Notably, PrEP usage was very low, with only 10% of individuals diagnosed with pharyngeal GC on PrEP. Most of these individuals would have been good candidates for PrEP before this diagnosis, and in hindsight, all would have a strong indication to start PrEP based on this diagnosis of pharyngeal GC.[27] There are a number of barriers to providing PrEP services at local health departments in North Carolina, including lack of funding, lack of prescribing protocols, absence of PrEP providers, lack of PrEP knowledge among staff in these health departments, and perceived lack of candidates for PrEP.[28] Clearly increasing access to PrEP for those we serve should be prioritized.

This study has several limitations. First, it was a single-center study, so our findings may not be generalizable to other settings in other geographic locations, particularly those outside of the public health setting. Second, our sample size was limited as this was a single-center study, which limited our ability to analyze the rates of positivity of GC specimens obtained at the TOC visits as we only had 41 people return for TOC. Still, our positivity rate of 2.4% is only slightly lower than those from other studies. Third, we relied on the accuracy of reporting in the EHR, so there may be a potential for reporting bias. Last, some individuals diagnosed with pharyngeal GC in our clinic may have had follow-up testing performed outside of our clinic, so we may have underestimated the true TOC rate.

In conclusion, we evaluated TOC rates after treatment of pharyngeal GC in a Sexual Health Clinic located in a local health department in the Southern United States and found low rates of return for TOC despite revised CDC guidance recommending this practice. To increase rates of return for TOC, alternative strategies for TOC should be investigated, such as implementing programs, so testing can be done at laboratory-only visits or at-home testing.

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