NACCHO[SM]
National Association of County & City Health Officials

Final Report

Pharyngeal Gonorrhea Test of Cure (TOC)

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Acknowledgements

The following is the final report of the National Association of County and City Health Officials' (NACCHO) Pharyngeal Gonorrhea (GC) Test of Cure (TOC) Project. Supported by the Centers for Disease Control and Prevention (CDC) Division of STD Prevention (DSTDP), the Pharyngeal GC TOC Project evaluated the yield of GC TOC to detect treatment failures following CDC-recommended first-line treatment and models and best practices for implementing pharyngeal GC TOC into routine clinical practice.

NACCHO wishes to acknowledge the four local health departments and/or associated STI clinics that were selected to demonstrate pharyngeal gonorrhea test of cure, the Public Health Institute at Denver Health, in Denver, CO; DC Health and Wellness Center, in Washington, DC; Maricopa County Department of Public Health, in Phoenix, AZ; and San Francisco City Clinic, in San Francisco, CA.

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Stock photos. Posed by models.

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Background

Neisseria gonorrhoeae (GC) represents the second most common notifiable sexually transmitted infection in the U.S., with a steady increase in reported cases since 2014.[1] In 2021, the Centers for Disease Control and Prevention (CDC) reported 710,151 cases nationwide,[1] marking the highest rate of GC incidence since the 1990s, and a more than 28% increase in cases since 2017.[1] Historically, underserved populations have borne a disparate burden of increases in GC infections, including gay, bisexual, and other men who have sex with men (MSM), transgender persons, sexual minority youth ages 13-24,[2] and Black, Latinx, American Indian/Alaskan Native, and Native Hawaiian/Pacific Islander persons.[1,3]

Without intervention, GC can result in serious sequelae, including pelvic inflammatory disease, ectopic pregnancy, infertility, epididymitis, and disseminated gonococcal infection, and can facilitate HIV acquisition and transmission.[4,5] Effective treatment of gonococcal infections can prevent adverse health outcomes.

Considered one of the top five antimicrobial resistance (AR) threat-level pathogens in the U.S., GC's ability to develop antimicrobial resistance has increasingly complicated treatment regimens for it.[6] Currently, the CDC recommends that uncomplicated cases of urogenital, anorectal, and pharyngeal GC be treated with a single dose of ceftriaxone 500mg intramuscularly.[7] Ceftriaxone is the last remaining highly effective drug available for empiric single-dose GC treatment and the only available drug that reliably cures gonorrhea at the pharynx. According to the 2021 CDC STI Treatment Guidelines, routine pharyngeal GC TOC with a nucleic acid amplification test (NAAT) or culture is recommended 7-14 days after treatment, regardless of regimen, due to the potential for persistent asymptomatic pharyngeal infection, the unclear penetration of recommended drugs at the pharynx, and the risk for antimicrobial resistance development.[8] However, the implementation of GC TOC for pharyngeal GC cases in routine clinical and public health practice has not previously been evaluated.

To demonstrate the implementation of pharyngeal GC TOC in clinical and public health settings, NACCHO and CDC DSTDP released a request for applications (RFA) in 2021 for the Pharyngeal Gonorrhea Test of Cure Project. The RFA funded four local health departments (LHDs) up to $100,000 to implement pharyngeal GC TOC, galvanizing local efforts to assess TOC for pharyngeal GC as a strategy to identify and prevent the spread of AR GC. Throughout the project period, NACCHO and CDC evaluated the feasibility of implementing TOC for all pharyngeal GC cases in clinical practice, the yield of pharyngeal GC TOC to detect treatment failures to CDC-recommended first-line treatment, and models and best practices for monitoring and responding to potential GC treatment failures. In addition, the evaluation explored how outcomes associated with TOC implementation varied across testing strategies (e.g., in-clinic vs. self-collection test kits).

Four LHD-run STI clinics were selected to implement pharyngeal GC TOC programs, whose demonstration project approach and results are reported below:

- **Public Health Institute at Denver Health, in Denver, CO**
- **DC Health and Wellness Center, in Washington, DC**
- **Maricopa County Department of Public Health, in Phoenix, AZ**
- **San Francisco City Clinic, in San Francisco, CA**

Intervention Sites

Table 1: Pharyngeal Gonorrhea Test of Cure Implementation Strategies

Implementation Strategies	Public Health Institute at Denver Health, Denver, CO	DC Health and Wellness Center, Washington, DC	Maricopa County Department of Public Health, Phoenix, AZ	San Francisco City Clinic, San Francisco, CA
TOC Electronic Health Record (EHR)Template/ Reports		X	X	
REDCap database for TOC data entry/reports		X		
Navigator/Dedicated TOC Staff	X TOC Project Assistant	X TOC Project Assistant	X Medical Assistant	
Non-clinic self-collection TOC Specimen Kit	X			X
In-clinic self-collection TOC specimen	X	X	X	X
In-clinic provider collection TOC specimen	X	X	X	X
Active Follow-Up Calls/ Texts/EHR Messages	X	X	X	X
TOC financial incentive			X	
In-House Laboratory			X	
Test of Cure Patient Education	X	X	X	X

Project Designs

Public Health Institute at Denver Health

Intervention Overview

Public Health Institute at Denver Health (PHIDH)'s pharyngeal GC TOC process enhanced work already underway at the clinic through the Strengthening the U.S. Response to Resistant Gonorrhea (SURRG) program. Coordinated through a partnership with the Colorado Department of Public Health and Environment and funded by the CDC, PHIDH's SURRG process enhanced surveillance of cases of gonorrhea.

To facilitate the pharyngeal GC TOC process, PHIDH leveraged existing SURRG staff and hired a part-time dedicated pharyngeal GC TOC staff member to provide the two reminder calls or messages via the electronic health record's patient portal. Patients were provided three options to provide a specimen for a pharyngeal GC TOC:

1. **In-clinic,**
2. **At-home self-collected test kit provided at the time of initial diagnosis and returned to the laboratory via mail, and**
3. **At-home self-collected test kit mailed to the home and returned to the laboratory via mail.**

Patients also received at least two reminders about pharyngeal GC TOC—one at the time of recommended pharyngeal GC TOC completion and one approximately 26 days following the treatment if they had not completed pharyngeal GC TOC. PHIDH used a commercial laboratory to process the at-home self-collection test kits.

Workflows

Denver Health incorporated pharyngeal GC TOC in its established gonorrhea workflows:

- **Pathway A:** clients with confirmed pharyngeal GC diagnosis at the time of treatment, and
- **Pathway B:** clients with unconfirmed pharyngeal GC diagnosis at the time of treatment.

Pathway A (known pharyngeal GC diagnosis at the time of treatment) steps included:

1. Provider delivered counseling on the need for pharyngeal GC TOC.
2. Client reviewed and chose between in-clinic or at-home self-collection pharyngeal GC NAAT. The client's reason for the pharyngeal GC TOC choice was documented. Staff educated all clients on self-collection techniques using a visual guide.
    a. For in-clinic pharyngeal GC TOC, the provider placed an order for a future test, and the client made a laboratory-only appointment before leaving the clinic.
    b. For at-home self-collection, the client could take an at-home self-collection test kit or have the kit mailed to them by the Program Assistant (PrA). The at-home self-collection test kit had English and Spanish instructions to guide self-collection, sample collection tubes, and a pre-paid return mailer.
3. The PrA called or sent a reminder message via MyChart (the EHR patient portal) one day before the planned

pharyngeal GC TOC.

4. The client performed a self-collected pharyngeal NAAT in-clinic or used an at-home self-collection test kit.
5. If pharyngeal GC TOC was not completed after 26 days, the PrA did a second follow-up reminder.
6. The PrA monitored pharyngeal GC TOC results and notified the SURRG nurse of positive tests.
7. The SURRG nurse notified clients of positive results and coordinated evaluation, repeated pharyngeal GC NAAT, GC culture, partner referral, and retreatment directed by the medical director. If a client with pharyngeal GC had an isolate with reduced susceptibility (RS) to ceftriaxone, the SURRG TOC process was used.

Pathway B (unconfirmed pharyngeal GC diagnosis at the time of treatment) included:

1. SURRG nurse performed weekly monitoring of the GC positive pharyngeal NAAT list and PrA reached out to clients regarding pharyngeal GC TOC.
2. The client was offered in-clinic or at-home self-collection of pharyngeal GC NAAT, documented the reason for selection, and provided self-collection instructions. The PrA ordered an in-clinic test with a laboratory-only visit or provided the client with an at-home self-collection test kit by pickup or mail.
3. Steps 3-7 are identical to those in Pathway A above.

Project Evaluation Plan and Outcomes

The project was evaluated using both quantitative and qualitative methods. The project logic model describes two main activities (See Figures 1-2):

1. Project implementation, and
2. Evaluation of feasibility and effectiveness.

Figure 1: Public Health Institute at Denver Health Pharyngeal Gonorrhea Test of Cure Program Logic Model Worksheet

PROGRAM LOGIC MODEL WORKSHEET

NAME OF PROGRAM/PROJECT:
Pharyngeal Gonorrhea Test of Cure Pilot Project

SITUATION:
-The newest CDC GC treatment guideline advises pharyngeal TOC for all patients. -Challenges: patient uptake of additional testing and clinic staff capacity for repeat testing/following up on patients regarding TOC.

INPUTS	OUTPUTS		OUTCOMES	
	Activities	Participants	Process Outcomes	Impact Outcomes
-MTL home GC/CT NAAT kit -Providers -Clinic staff -Program Assistant -Program Director/SURRG Nurse -Medical Director -Patients with positive pharyngeal GC -Denver Health Laboratory pharyngeal NAAT, GC culture, AST -EMR -Data Analyst -DPTC -CDPHE	-Implement the pharyngeal TOC project. -Evaluate the feasibility and effectiveness of pharyngeal TOC project.	-Patients -Providers -Clinic staff -Program Assistant -SURRG Nurse -Medical Director -Data Analyst	Start pharyngeal GC TOC process by 4/15/21. Primary and secondary outcome data variables are finalized by 4/30/21. Primary and secondary outcome data analysis plan is developed by 4/30/21. By 5/31/21, fine-tune and finalize the pharyngeal TOC process based on initial round of patient survey results/ primary and secondary outcomes data. Staff time/cost needed to implement the pharyngeal GC TOC program will be assessed by 2/28/22. By 2/28/22, analyze client survey (continuous) and provider feedback (February 2022) results. By 3/31/22, complete an evaluation of the feasibility and effectiveness of pharyngeal TOC project, by assessing primary and secondary outcome data (see evaluation plan below).	Pharyngeal GC TOC response rate will be measured to evaluate the effectiveness of pilot project. The DSHC demonstrates the feasibility and define barriers to pharyngeal GC TOC process by 3/31/22. By 4/15/22, summarize and disseminate the pilot project summary through DPTC, NACCHO, and other conference opportunities.

GC, gonorrhea; TOC, test of cure; CDC, centers for disease control and prevention; MTL, Molecular Testing Labs; CT, chlamydia; NAAT, nucleic acid amplification test; SURRG, Strengthening the U.S. Response to Resistant Gonorrhea; AST, antimicrobial susceptibility testing; EMR, electronic medical record; DPTC, Denver Prevention Training Center; CDPHE, Colorado Department of Public Health and Environment; DSHC, Denver Sexual Health Clinic

Figure 2: Public Health Institute at Denver Health Pharyngeal Gonorrhea Test of Cure Program Evaluation Plan

EVALUATION PLAN:

Quantitative Data:
Primary outcomes (TOC response rate)
Data on feasibility of program implementation:

- Number of follow-up/reminder calls & time spent per client by Program Assistant
- Time spent per client by provider/Program Assistant on counseling regarding TOC and self-collection of NAAT
- Time spent to monitor list of positive pharyngeal GC clients
- Time to monitor TOC results
- Staffing time for management of positive TOC results
- Cost of pharyngeal TOC testing

Secondary outcomes:

- Predictors of pharyngeal GC TOC uptake (demographic information)
- Average time to TOC from time GC treatment, stratified by mode of TOC (in-clinic versus home testing)
- Type of diagnostic test performed at TOC (NAAT and/or culture)
- Reasons for positive TOC – reinfection, delayed clearance, cephalosporin resistance, inadequate initial treatment regimen, and unknown reason
- Treatment regimen that cleared the positive TOC
- Client preference on mode of TOC
- TOC adherence, stratified by mode of TOC

Qualitative Data:

- Initial client survey (5 clients from in-clinic testing and 5 clients from home testing) and provide feedback (2)
- Continuous patient survey (at least 50% patients) on reasons for TOC uptake & feedback on the follow-up process, barriers, and facilitators for TOC completion
- Provider feedback (4) on the TOC process and additional time/effort spent on counseling clients about TOC

An initial qualitative assessment was collected in May 2021 to guide the final program design. A small number of client survey results and provider feedback surveys were used to fine-tune the pharyngeal GC TOC process. (See Figures 3-4.)

Figure 3: Public Health Institute at Denver Health Pharyngeal Gonorrhea Test of Cure Uptake Client Survey Questions

Pharyngeal Gonorrhea Test of Cure (TOC) Uptake Client Survey Questions

Purpose:

- To find out reasons why client completed TOC.
- To seek feedback for the pharyngeal gonorrhea TOC process for improvement.

Logistics:

- Program Assistant will call a client who completed TOC and ask if they will answer four questions about the TOC process.
- Collect response in spreadsheet without client identifiers.

Questions:

1. Which TOC method did you choose and why?
2. How convenient was your TOC option (in-clinic or home testing), if not convenient, how can it be improved?
3. Why did you complete TOC (select all that apply)?
    a. The importance of TOC was explained by my provider.
    b. I understand the importance of TOC (important for my own health).
    c. The convenience of TOC option chosen.
    d. The follow-up/reminder call was helpful.
    e. It was confidential.
    f. I did not need transportation.
    g. I could complete it without taking time off from work or other commitments.
    h. Other reasons, please specify
4. Is there anything that can be done to improve the TOC process?

Figure 4: Public Health Institute at Denver Health Pharyngeal Gonorrhea Test of Cure Uptake Provider Questions

Pharyngeal Gonorrhea Test of Cure (TOC) Uptake Provider Questions

Purpose:

- To find out client preference and reasons for mode of TOC.
- To seek feedback for the pharyngeal gonorrhea TOC process for improvement.
- To identify mechanism to reduce staff burden on implementing TOC.

Logistics:

- Program Assistant will interview providers.
- Collect response in spreadsheet.

Questions:

1. On average, how long did it take you to explain the importance of pharyngeal GC TOC?
    a. Quickly (1-2 minutes)
    b. Some time (5 minutes)
    c. Extensively (6-10 minutes)
    d. Other, explain
2. On average, how long did it take you to educate client about self-collection of pharyngeal specimen?
    a. Quickly (1-2 minutes)
    b. Some time (5 minutes)
    c. Extensively (6-10 minutes)
    d. Other, explain
3. Which job aid(s) did you use?
    a. Just demonstration
    b. Using a visual aid
    c. Other, explain
4. Anything can be done to improve the process? Are there tools that would reduce staff burden?

Impact outcomes of this project included pharyngeal GC TOC response rate (between 7-30 days), assessment of the feasibility of the pharyngeal GC TOC process, and dissemination of a project summary. Pharyngeal GC TOC data was aggregated and stratified by mode of pharyngeal GC TOC (in-clinic versus at-home testing) to determine which was most frequently selected and which was associated with the highest pharyngeal GC TOC completion rate.

The feasibility of program implementation, especially the impact on clinic capacity, including time/cost needed for pharyngeal GC TOC activities, was estimated by PrA and nurse time log and expense monitoring. Time and cost were determined and compared for in-clinic versus at-home pharyngeal GC TOC processes. Client surveys were offered via phone for clients who completed pharyngeal GC TOC. Quantitative secondary outcome data included analysis of predictors of pharyngeal GC TOC uptake, including gender identity, sexual orientation, age, race/ethnicity, HIV status, HIV pre-exposure prophylaxis use, and antimicrobial minimum inhibitory concentration (MIC) results. The average time to pharyngeal GC TOC from pharyngeal GC treatment was compared for in-clinic and at-home self-collection test kit pharyngeal GC TOC.

The project evaluated clients with a positive pharyngeal GC TOC NAAT to determine the proportion attributable to reinfection, delayed clearance, inadequate initial treatment regimen, or ARGC. It tracked the regimens that subsequently cleared the infection. These evaluations were initiated in the first month of the project and completed during the final month to prepare to disseminate lessons learned.

Results

PHIDH reported that of 301 cases of pharyngeal GC treated among 285 individuals during their study period (approximately May 2021-May 2022), the median client age was 29 years [IQR=26-34]. The 285 individuals were 78% cis-gender male, 44% White, 40% Hispanic, and 10% Black. Of the 301 cases, 280 (93%) were successfully contacted, and a pharyngeal GC TOC option was selected. The remainder (7%) of pharyngeal GC cases were considered lost to follow-up. More clients chose in-clinic (176/280, 63%) than at-home pharyngeal GC TOC (104/280, 37%). The pharyngeal GC TOC completion rate was 66% (200/301) for all clients, and 71% (200/280) for clients who were successfully offered pharyngeal GC TOC. In-clinic pharyngeal GC TOC completion was 74% (131/176), and at-home completion was 66% (69/104). Positive pharyngeal GC NAAT TOCs were uncommon (8/200; 4 %) and were attributed to residual nucleic acids from nonviable organisms (3.5%; n=7) and reinfection (0.5%; n=1).

Overall, 28% (55/200) of clients who completed a pharyngeal GC TOC were successfully contacted for survey completion and completed the pharyngeal GC TOC survey via telephone. Of these, 34 clients completed the in-clinic pharyngeal GC TOC test, and 21 completed the at-home pharyngeal GC TOC test. The clients who chose the in-clinic pharyngeal GC TOC option reported that the reasons for choosing this option included provider recommendation (47%, 16/34), convenience (18%, 6/34), perceived test accuracy (12%, 4/34), and not wanting to deal with mailing samples (12%, 4/34). Those who selected other reasons (6%, 2/34) noted they did not want to self-collect the pharyngeal sample, already had an in-clinic follow-up visit scheduled, wanted a quicker result, and felt they did not have privacy at home. Those clients who chose the at-home pharyngeal GC TOC option reported that the reasons included convenience (71%, 15/21), inability to take time away from work/school (24%, 5/21), and provider recommendation (19%, 4/21). The majority of clients who responded to the survey thought the pharyngeal GC TOC option was somewhat convenient (25%, n=14) or very convenient (53%, n=29). Seven clients said the pharyngeal GC TOC option was very inconvenient (2%, n=1) or somewhat inconvenient (11%, n=6). Reported reasons for TOC completion included wanting to make sure infection is cleared (self-motivation) (91%, 50/55), provider counseling and education (35%, 19/55), the convenience of TOC option (7%, 4/55), and reminder calls and messages were helpful (7%, 4/55).

Furthermore, the provider feedback survey was collected after the initial three months of program implementation. Provider feedback survey responses (n=5) on what they learned about offering pharyngeal GC TOC were that it only took about 1-4 minutes to counsel patients about pharyngeal GC TOC, and for at-home pharyngeal GC TOC, it only took an additional 1-4 minutes to advise about the logistics. Sixty percent of providers (3/5) used the pharyngeal GC TOC intervention as a teaching method. Mid-point staff training was done on November 1, 2021, to review the survey results, share data, and update the pharyngeal GC TOC timeframe, especially for home self-collection testing, to at least 14 days after treatment.

Challenges and Lessons Learned

PHIDH learned that working closely with stakeholders, such as providers, nurses, nurse practitioners, lab technicians, and Epic analysts, facilitated buy-in and ensured the smooth integration of the program into the clinic's workflow. However, several challenges and lessons learned arose. The intervention relied on the Epic system to track and remind providers about the pharyngeal GC TOC protocol. However, there were concerns about “pop-up fatigue” caused by multiple reminders for different protocols being flagged on each client’s chart.

The Program Assistant, who served as the patient navigator, proved particularly helpful in implementing pharyngeal GC TOC and could be readily integrated into the intervention, helping providers handle reminder calls and outreach to patients. Other emerging concerns included patient confidentiality, increased testing budgets, time constraints, staff turnover, and burnout. These were addressed by gathering client and provider feedback via surveys and interviews, which assessed the program's effectiveness and provided guidance to make ongoing improvements as needed. PHIDH also recommended creating checklists and a toolkit to facilitate program implementation, ensuring its successful uptake and integration into clinical systems. It also was notable that patients varied in their pharyngeal GC TOC approach, with some clients preferring to come into the clinic and others opting to mail in their tests. Offering both approaches might be best in the long run.

DC Health and Wellness Center

Intervention Overview

The DC Health and Wellness Center (DCHWC) project included a modified approach to their test of reinfection (TORI) Quality Improvement project, which encouraged patients who tested positive for GC to return in three months for a TORI per CDC guidelines. In the modified approach, all patients with a positive pharyngeal GC test were scheduled for a follow-up test in 7–14 days for pharyngeal GC TOC. Patients were strongly counseled to refrain from receptive oral sex (or to use barrier protection) until the completion of the pharyngeal GC TOC visit.

At the follow-up visit, the clinician collected some additional information from the patient, obtained the pharyngeal GC TOC sample, and sent the repeat test to a contract laboratory. If the repeat test was positive, the patient was called by the TOC project assistant (in this instance, a part-time research assistant) to present for retreatment and re-testing. At this visit, the clinician collected an additional specimen for repeat GC NAAT as well as a sample plated on an In-Tray agar for culture. If successfully cultured and confirmed positive by GC NAAT, the specimen was sent to the CDC for further characterization, and antimicrobial susceptibility testing (AST) results were communicated with the clinic through a secure file share.

To optimize pharyngeal GC TOC uptake, a report was run through the DCHWC eClinicalWorks EHR system on Monday, Wednesday, and Friday morning of all patients receiving a positive pharyngeal GC NAAT within the last 21 days, and those patients were added to a shared REDCap (Research Electronic Data Capture) system, a HIPAA-compliant database, on the DC government encrypted server. Once individuals were added to the list, they were called up to three times by the TOC project assistant, who discussed the pharyngeal GC TOC guidelines and the recommendation to return for TOC testing in 10-14 days. The patient was scheduled for a return test using the new Pharyngeal GC TOC Clinical Appointment Type. Per standard clinical protocol, the patient received a text message reminder 24 hours before their scheduled appointment.

As the project went on, it was found to be most efficient for the clinician to schedule the TOC appointment at the time of treatment, or time of discussion of results if the patient had been treated empirically. If an appointment was not scheduled in that manner, or the patient missed that appointment, then the TOC project assistant would call the patient.

Additionally, DCHWC included in the study protocol the opportunity for universal $20 incentives if the rate of return for pharyngeal GC TOC testing was below 50% six months after initiation of the program. In that scenario, patients would have been given an incentive for each touchpoint with the clinic, including the initial pharyngeal GC TOC return visit and any additional necessary visits for AST and genotype testing if the initial pharyngeal GC TOC test was positive. Since participation rates were always greater than 50%, the incentives were not implemented.

Project Evaluation Plan and Outcomes

Process measures to be evaluated included those displayed in the chart below. AST and genotypic data were also collected and analyzed monthly.

Table 2: DC Health and Wellness Center Proposed Process and Outcome Measures

Activity	Process Measure	Outcome Measure
Testing and Initial Treatment	• Number of pharyngeal GC tests • Number of positive pharyngeal GC tests	• Nasopharyngeal GC burden as a percentage of services offered • Feasibility of implementing pharyngeal GC TOC • Feasibility of identifying antimicrobial-resistant GC • Identifying best practices and gaps to facilitate pharyngeal GC TOC • Identifying total yield of pharyngeal GC TOC • AST Data for positive pharyngeal GC TOC tests • Number of positive pharyngeal GC TOC with ceftriaxone MIC >0.25 µg/mL
Linkage	• Number of calls made for linkage • Days elapsed between calls • If needed, the number of incentives offered	

Test of Cure (pharyngeal GC TOC)	• Number and percentage of people who returned for pharyngeal GC TOC within 7-30 days
	• Number of positive infection results at pharyngeal GC TOC and type of disposition of positive cases (reinfection vs. delayed clearance vs. alternative regimen)
	• Number of positive pharyngeal GC TOC sent to CDPHL
	• Number of positive pharyngeal GC TOC viable for culture
	• Number of culture viable pharyngeal GC TOC sent to CDC WGS
	• Number and percentage of treatment failures
		• Clinical capacity used for pharyngeal GC TOC
		  • Appointment times used for pharyngeal GC TOC
		  • Staff time used for pharyngeal GC TOC follow-up

At the mid-point of the project, DCHWC made some changes to their protocol, including creating and utilizing a REDCap database for data entry, as it had proven difficult to capture the complete data needed for project reporting within the EHR. One of the biggest changes was to implement the scheduling of the pharyngeal GC TOC visit directly by the provider at the time of the pharyngeal GC treatment visit or during the phone call when results were discussed if the patient was empirically treated. In addition, the goal time to schedule TOC was adjusted from 7-14 days to 10-14 days due to several episodes of positive TOC samples likely related to lingering genetic material.

DCHWC's outcome goals included having 100% of pharyngeal GC cases treated within 14 days of diagnosis, a 75% pharyngeal GC TOC return rate for clinic patients, and a 75% return rate for confirmation testing and retreatment of patients with positive pharyngeal GC TOC.

Between May 1, 2021, and April 30, 2022, 3233 pharyngeal GC tests were performed at the DCHWC. Of those, 190, or 6%, received a positive test result, of which 187 (98%) were treated according to CDC STI treatment guidelines, and 174 (93%) were scheduled for a pharyngeal GC TOC visit. 135 of those 174 (78%) completed the pharyngeal GC TOC, and a total of 10 pharyngeal GC TOC pharyngeal GC swabs were positive. One of the 10 positive pharyngeal GC isolates viable for culture underwent AST testing, and was sent to the CDC for whole genome sequencing (WGS). Based on AST,

the isolate was susceptible to ceftriaxone (initial treatment).
Some of the key demographic findings from the project included:

- 6% of the clients identified as transgender women, markedly higher than in the general population and the population categorized under current surveillance data for STIs in Washington, DC.
- 79% of clients identified as male and 15% identified as female.
- 36% of clients identified as ethnically Hispanic.
- 46% of the clients identified their race as African American, and 30% identified as Caucasian, 3% as Asian, 2% as Native Hawaiian/ Alaskan Native, 19% Unknown/Not Specified.

Challenges and Lessons Learned

Throughout the project period, DCHWC had a solid rate of return for pharyngeal GC TOC (~75%), and they found the inclusion of pharyngeal GC TOC in their clinic workflow to be manageable once the structures were in place. The dedicated project assistant who conducted outreach to patients for follow-up made this effort feasible for a clinic with otherwise limited staffing. DCHWC identified a few cases of GC reinfection that were able to be treated in a timely manner, which also helped them determine the best timing for pharyngeal GC TOC testing.

Some of the elements of the project that were crucial for successful implementation were templates in the EHR system to capture all relevant data elements, close partnership with the public health laboratory, and usage of a data collection tool for patient tracking. Regular evaluation and updates to the processes were also important, such as the protocol adjustment to schedule clients' TOC appointments at the time of their treatment or immediately after receiving treatment results, or adjusting the TOC timing to 10-14 days after identifying several positive TOC results that were likely due to remaining genetic material. Clear protocols, ongoing evaluation and staff training, and dedicated team members were the keys to successful implementation of this project.

Maricopa County Department of Public Health

Intervention Overview

The Maricopa County Department of Public Health (MCDPH) STD Clinic incorporated the pharyngeal GC TOC within their clinic workflow and existing EHR infrastructure. Three different EHR templates were utilized to capture data for the project: (1) Initial Provider Visit Template; (2) Test of Cure Specimen Collection Template; and (3) Positive Test of Cure Follow-Up Visit Template. While the latter two templates were newly developed for this project, the Initial Provider Visit Template was pre-existing and modified to capture data elements specific to the initial pharyngeal GC visit. Use of the existing EHR, eClinicalWorks, was performed to streamline the pharyngeal GC TOC process for increased efficiency, a key priority for both patients and the clinic.

The process began at the time of initial pharyngeal GC treatment. During the appointment, providers completed the Initial Provider Visit Template to capture demographic, behavioral, and clinical-based questions related to the initial pharyngeal GC infection. Before the patient left the clinic, the medical provider scheduled an appointment for the patient to return for an in-clinic pharyngeal GC TOC, within 7-30 days. This on-site appointment-based model differed from the MCDPH STD clinic's typical walk-in services, helping patients easily return for their pharyngeal GC TOC visit. Additionally, beginning November 1, 2021, a $10 gas card was offered to incentivize patients to attend their pharyngeal GC TOC appointment.

Medical assistants subsequently provided three reminder phone calls for patients to return for their pharyngeal GC TOC appointment. Patients who did not attend their scheduled pharyngeal GC TOC appointment were contacted by a medical assistant to reschedule. Patients who did attend were seen by a medical assistant for pharyngeal GC TOC specimen collection and completion of the Test of Cure Specimen Collection Template (See Figure 5). The pharyngeal GC TOC specimen was delivered to the public health laboratory. If the pharyngeal GC TOC was negative, no further

follow-up occurred. If positive, the patient was notified of their results and asked to return to the clinic for additional treatment and a repeat specimen collection for culture and AST. At follow-up, medical providers completed the Positive Test of Cure Follow-Up Visit Template.

Integrating data collection into EHR templates allowed minimal changes to provider workflow and patient experience. eClinicalWorks Business Optimizer was utilized to create a custom report to compile data elements across the three employed templates. A secondary custom report was built to capture any individuals positive for pharyngeal GC who were routed through the MCDPH STD Clinic's express testing but did not return for a provider visit. All data were imported, cleaned, and analyzed using SAS Enterprise Guide 8.2.

Project Evaluation Plan and Outcomes

During the implementation period from September 1, 2021, through July 31, 2022, MCDPH identified a total of 983 pharyngeal GC positives (See Figure 6). Of these, 891 (90.6%) were documented as receiving treatment. Among treated individuals, 316 (35.5%) completed the pharyngeal GC TOC with a median time to appointment of 17.5 days. Of those attending the pharyngeal GC TOC appointment, MCDPH noted a median of 3 total clinic visits and a median of 2 total phone call reminders.

Overall, MCDPH identified 17 (5.4%) total positive pharyngeal GC TOCs among treated individuals. Among these, 13 (76.5%) could not be dispositioned due to missing cultures and/or behavioral risk factor documentation. Among the remaining 4 positive pharyngeal GC TOCs, 2 (15.4%) were determined to be likely reinfections, and 2 (15.4%) were likely false positives due to residual genetic material post-treatment. Of the 17 individuals with positive pharyngeal GC TOC, 11 (64.7%) returned for retreatment, while 6 (35.3%) were lost to follow-up.

The primary outcome measures identified to be examined by MCDPH were:

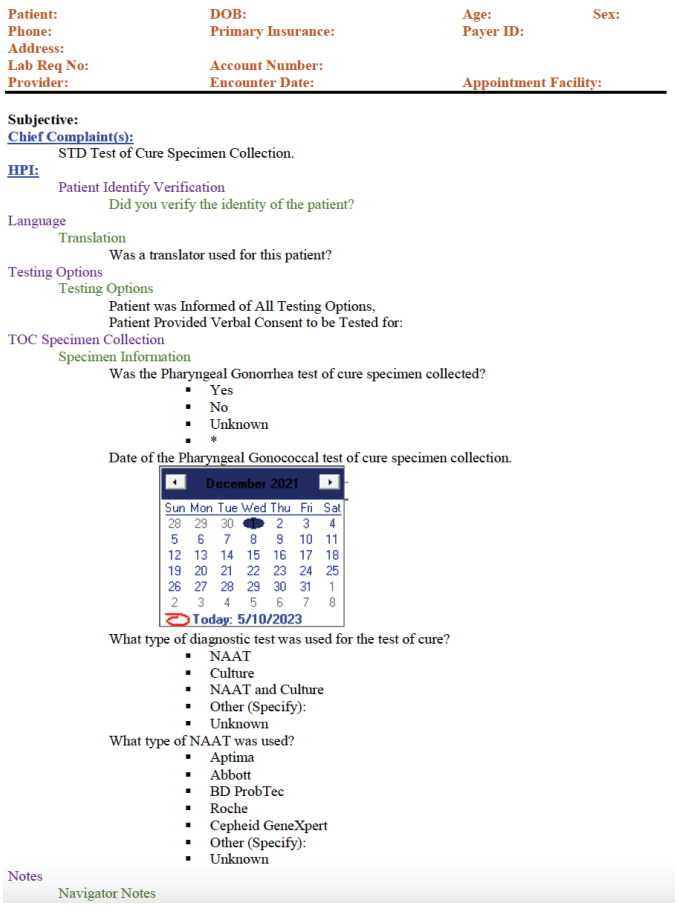
1. How feasible was the pharyngeal GC TOC project to implement? As indicated by:
    - Number of staff working in the project area that experienced workflow disruption,
    - Types of workflow disruptions,
    - Several staff indicated they are satisfied with the project, and
    - Number of full-time employees (FTEs) (by skill type) needed to administer the project.
2. What barriers and facilitators affected the implementation? As indicated by:
    - Number of patients that experienced transportation issues,
    - Number of participants who complied to return for follow-up test,
    - Number of providers and staff who received training on pharyngeal GC TOC, and
    - Number of contact attempts for follow-up.
3. How does pharyngeal GC TOC implementation impact other clinic services and staffing needs? As indicated by:
    - Number of TOC NAAT specimens received in the laboratory and how it affects workflow,
    - Number of pharyngeal GC TOC cultures received in laboratory and how it affects workflow, and
    - Number of shipments of pharyngeal GC TOC specimens to CDC and how it affects workflow.
4. To what extent did the pharyngeal GC TOC project reach the intended targets and outcomes? As indicated by:

- Number of participants receiving pharyngeal GC TOC 7-30 days after treatment,
- Number of patients treated for pharyngeal GC,
- Number of patients who tested positive after returning for pharyngeal GC TOC, and
- Number of patients who tested positive after returning for pharyngeal GC TOC and had a GC culture.

Secondary outcome measures identified were:

1. Average time to pharyngeal GC TOC.
2. Type of diagnostic test performed.
3. How many GC cases had positive pharyngeal GC TOC?
4. How many patients with positive pharyngeal GC TOC are suspected to be reinfected?
5. How many patients with positive pharyngeal GC TOC were treated with an alternative regimen?
6. How many patients with positive pharyngeal GC TOC had cephalosporin resistance concerns?
7. How many patients had positive pharyngeal GC TOC with unknown reasons for treatment failure?
8. What treatment regimens cleared the infection?

Figure 5: Medical Assistant Pharyngeal Gonorrhea Test of Cure Specimen Collection Template, Maricopa County



Patient: **DOB:** **Age:** **Sex:**
Phone: **Primary Insurance:** **Payer ID:**
Address:
Lab Req No: **Account Number:**
Provider: **Encounter Date:** **Appointment Facility:**

Subjective:
Chief Complaint(s):
STD Test of Cure Specimen Collection.
HPI:
Patient Identify Verification
Did you verify the identity of the patient?
Language
Translation
Was a translator used for this patient?
Testing Options
Testing Options
Patient was Informed of All Testing Options,
Patient Provided Verbal Consent to be Tested for:
TOC Specimen Collection
Specimen Information
Was the Pharyngeal Gonorrhea test of cure specimen collected?
- Yes
- No
- Unknown
- *

Date of the Pharyngeal Gonococcal test of cure specimen collection.

December 2021

Sun	Mon	Tue	Wed	Thu	Fri	Sat
28	29	30		2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	1
2	3	4	5	6	7	8

Today: 5/10/2023

What type of diagnostic test was used for the test of cure?
- NAAT
- Culture
- NAAT and Culture
- Other (Specify):
- Unknown

What type of NAAT was used?
- Aptima
- Abbott
- BD ProbTec
- Roche
- Cepheid GeneXpert
- Other (Specify):
- Unknown

Notes
Navigator Notes

Challenges and Lessons Learned

Delays in transitioning to a new system for collecting pharyngeal GC TOC data slowed the implementation of the project's data collection templates until September 1, 2021. Despite the delay, project integration into the clinic's EHR system served as the primary facilitator of pharyngeal GC TOC by minimizing disruptions to clinical workflow. However, challenges remain related to the additional time required to validate extracted data elements for quality assurance. Moreover, reminder calls still need to be conducted manually, though MCDPH intends to leverage the EHR system to automate and implement text messaging reminders.

Moving forward, given the high client volume experienced by the MCDPH STD clinic and the related data entry workload for providers, MCDPH will reduce the number of pharyngeal GC data elements requested on the Initial Provider Visit Template. This should alleviate providers' data entry burden. In response to challenges in identifying returning clients with positive pharyngeal GC TOC, MCDPH has conducted regular quality assurance to review these clients and ensure cultures are collected at follow-up. As a result, provider awareness and communication with the public health laboratory has improved. MCDPH plans to develop a lab ask-at-order entry to facilitate the prompting of the public health laboratory for sending cultures for AST.

MCDPH ultimately found that over a third of clients were amenable to returning for a TOC specimen collection in the project period. However, implementing the pharyngeal GC TOC project in high-volume settings poses challenges. In alignment with CDC recommendations, MCDPH will continue to offer in-person pharyngeal GC TOC appointments to all patients with pharyngeal GC.

San Francisco Department of Public Health: SF City Clinic

Intervention Overview

The San Francisco City Clinic's (SF City Clinic) TOC project was designed to assess the feasibility of obtaining pharyngeal GC TOC 7-14 days after treatment for all patients diagnosed with and treated for pharyngeal GC at the clinic. The SF City Clinic integrated pharyngeal GC TOC into their clinic workflow.

At SF City Clinic, pharyngeal GC testing is offered to all MSM and transgender persons who have sex with men who report receptive oral sex in the prior three months. The testing was primarily conducted on-site using the Cepheid GeneXpert. For patients with an indication for empiric treatment (e.g., GC urethritis or contact with GC), the pharyngeal swab specimen was sent to the SFDPH's public health laboratory, where the Aptima GC NAAT test was performed.

Pharyngeal GC TOC was offered to all patients diagnosed with pharyngeal GC.
As a Gonococcal Isolate Surveillance Project (GISP) and SURRG site, GC cultures are routinely collected in the following clinical scenarios:

1. **Patients presenting with a clinical syndrome consistent with GC;**
2. **Patients with a positive GC NAAT returning for treatment (including patients with a positive pharyngeal GC TOC); or**
3. **Patients who reported contact with GC.**

SF City Clinic offered two options for patients receiving a pharyngeal GC TOC:

1. **At-home self-collection test as the primary strategy; and**
2. **In-clinic self-collection.**

All patients diagnosed with pharyngeal GC were offered a kit to take with them at the time of treatment and received a follow-up text 7 days after the visit. If the clinic staff did not receive the self-collected test kit within 14 days of the visit, the patient was contacted by phone and text, reminded to send in the test kit, and offered an option to return in

person for pharyngeal GC TOC. Before starting this study, the San Francisco Public Health laboratory validated self-collected pharyngeal specimens for use with their Aptima CT/GC test (Hologic).

Patients diagnosed with pharyngeal GC but who had already been empirically treated (i.e., positive GC NAAT result returned after a visit, but no additional treatment needed) were contacted by phone and offered to either return in person or receive a self-collection kit by mail. They received one text reminder if they did not come in for their appointment or return their self-collection kit. Patients who opted to return in-person were offered a non-clinician "express" visit.

All patients with positive pharyngeal GC TOC were contacted and asked to return for additional testing and treatment. At the return visit, patients with a positive pharyngeal GC TOC were seen by a clinician who conducted an interim risk assessment and collected pharyngeal swabs for repeat GC NAAT and GC culture. Patients with suspected treatment failure were empirically re-treated with an antimicrobial regimen as determined by the evaluating clinician.

Project Evaluation Plan and Outcomes

The SF City Clinic TOC project involved a cross-disciplinary team that included clinical providers, nurses, a disease intervention specialist (DIS), clerical staff, epidemiologists, and IT specialists and built on existing, well-vetted systems to integrate pharyngeal GC TOC into existing workflow as opposed to creating something entirely new. The project team used the existing data infrastructure and patient assignment system to identify eligible patients, perform follow-ups and reminders, and hold multi-disciplinary meetings to review workflows and data and to strategize adaptation to current practice when necessary. As designed, the primary outcome of the demonstration project was the proportion of individuals with pharyngeal GC who had a repeat GC NAAT performed within 7-14 days of diagnosis.

Secondary outcomes were:

- Proportion of patients who had pharyngeal GC TOC conducted stratified by race/ethnicity, age, gender, sex of sex partners, and number of sex partners in three months prior to diagnosis;
- Proportion of pharyngeal GC TOC specimens that were collected at return in-person visit vs. self-collected not in the clinic setting;
- Number of self-collection test kits distributed, and number and percentage returned by mail within 14 days;
- Number and percentage of patients who required additional reminders to prompt follow-up with pharyngeal GC TOC; and
- Number of pharyngeal GC TOCs that required in-person clinic visits.

Among those that had pharyngeal GC TOC conducted outcomes encompassed:

- Time to pharyngeal GC TOC;
- Number and percentage with positive NAAT;
- Of those with positive NAAT at pharyngeal GC TOC, the number and percentage who reported receptive oral sex after treatment and prior to pharyngeal GC TOC;
- Of those with positive NAAT at pharyngeal GC TOC, the number and percentage with positive culture; and
- Of those with a positive culture, the number and percentage of specimens exhibited reduced susceptibility to cefixime or ceftriaxone.

Challenges and Lessons Learned

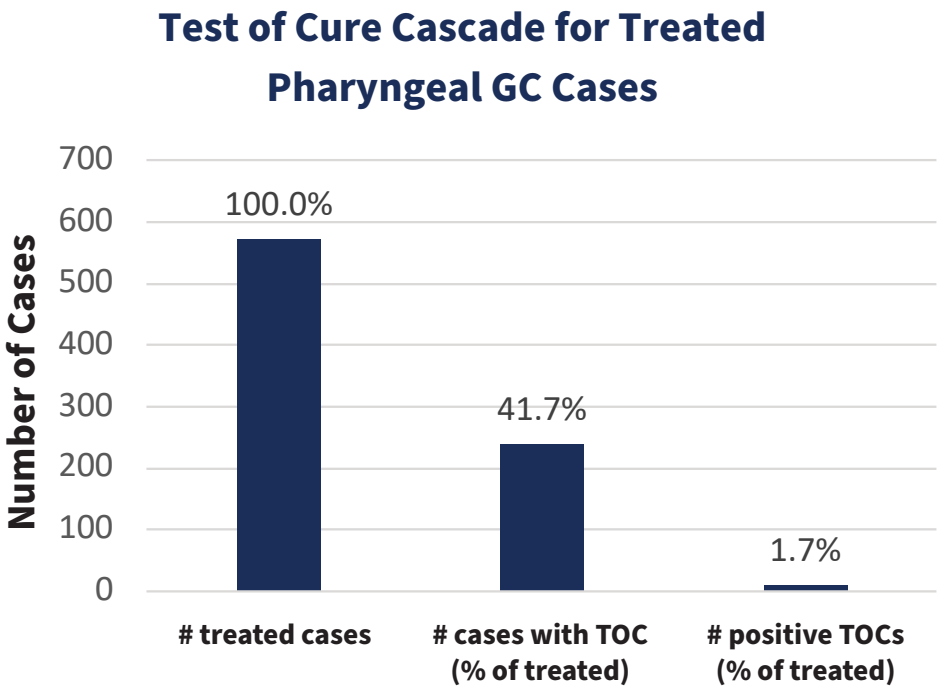
The SF City Clinic found that clients often required additional educational support to understand why they needed to participate in pharyngeal GC TOC. Timing and contacting client participation for pharyngeal GC TOC follow-up often proved challenging. The clinic also found a disconnect in communication between staff and clients due to language barriers. The clinic additionally noted that staff unexpectedly had to handle requests for testing results from clients who used self-collect kits. Results from these kits previously had not been made available in clients' data portals, which the clinic had to rectify. Limitations in staff time also meant they could not follow up with patients to assess their experience with pharyngeal GC TOC and adjust as necessary. SF City Clinic transitioned to a new EHR during the project, which required adjustments to the reports and tracking process.

They also identified the next steps for implementation, including the addition of capacity for patients to check their self-collected test results for pharyngeal GC TOC online, and evaluation, notably the expansion of the project's feasibility as part of the evaluation. This included attempts to quantify the amount of staff time being spent on the project per week and the potential evaluation of the patient experience of pharyngeal GC TOC (i.e., ease, access, satisfaction).

There were several notable challenges to evaluation at the mid-point of the project, including the competing focus of COVID-19 and the complexity of evaluating the significance of a positive pharyngeal GC TOC, since it was only sometimes a clear treatment failure.

SF City Clinic ultimately reported limitations to the usefulness of pharyngeal GC TOC. Client uptake of pharyngeal GC TOC was relatively low (approximately 40%). Uptake of the home-testing option for TOC was lower than expected. The clinic integrated kit distribution into the workflow and across disciplines (as opposed to one point of contact) and allowed patient pharyngeal GC TOC self-collection in-clinic after the initial diagnosis. Positive pharyngeal GC TOC ultimately was low throughout the project, and very few positive TOCs were suspected to represent true treatment failure.

Figure 7: San Francisco Department of Public Health Test of Cure Cascade for the Project, May 1, 2021 - May 31, 2022



Cross-Site Outcomes

Methods

Demographic, behavioral, and clinical data were collected and submitted to CDC quarterly by participating project sites for each episode of pharyngeal gonorrhea managed (i.e., treated, pharyngeal GC TOC coordinated) at the participating STD clinic. (See Appendix). Sites assigned a unique identifier to each patient, allowing for longitudinal tracking and linkage of patients with epidemiologic and clinical data to lab results. Sites were provided with a standardized project data template and data dictionary.

Each site had at least one staff representative participate in two virtual interviews: a mid-point interview in December 2021 and an end-of-project interview in August 2022. Each site also completed a final implementation progress report, which included a few survey questions related to sustainability and the technical assistance received. In addition, sites conducted a local evaluation to assess their implementation and outcomes (e.g., number of cases, pharyngeal GC TOC completion rate, pharyngeal GC TOC positivity rate).

Results

The four project sites diagnosed 1,968 pharyngeal GC infections during the study period, approximately May 2021-May 2022, among 1,783 unique patients. The majority (90%) received CDC-recommended first-line treatment with ceftriaxone. Among 1,829 treated cases across the four sites, the pharyngeal GC TOC completion rate was 46%; the pharyngeal GC TOC completion rate varied by site (range: 36% – 71%). Across all project sites, the median time between treatment and pharyngeal GC TOC was 14 days (interquartile range: 14–18). Among those with pharyngeal GC TOC performed, 5% (n=39) were positive by NAAT. Of these, 49% had GC culture attempted; six positive pharyngeal GC TOCs (15%) were also positive by culture.[11]

The yield of pharyngeal GC TOC to detect treatment failures was low; ceftriaxone treatment failure was rare (n=5; <1%), and there were no cases of cephalosporin-resistant GC detected.[11] Six positive pharyngeal GC TOC cases (15%) could not be dispositioned due to missing data (i.e., patient was lost-to-follow-up).

Feasibility

Testing

All of the sites reported that implementing pharyngeal GC TOC was feasible. For the two sites that offered both in-clinic and at-home self-collection test kit specimen collection, when given a choice, patients tended to choose in-clinic over at-home self-collection. In-clinic engagement was associated with a higher completion rate compared to non-in-clinic options. Denver Health's completion rates for pharyngeal GC TOC were 63% for in-clinic testing and 37% for at-home self-collection (overall pharyngeal GC TOC completion rate was 66%). In comparison, SF City Clinic reported approximately 50% of all pharyngeal GC TOC was collected via at-home-self-collection. Sites reported that patient education seemed to improve the rate of return by highlighting the importance of pharyngeal GC TOC.

Workflow Integration

Project sites did not report significant disruptions to their clinic workflow because of pharyngeal GC TOC implementation. One site noted that because of their use of existing EHR infrastructure, changes to that system should be carefully considered in order to not impact other processes. Furthermore, pharyngeal GC TOC was well-integrated into the sites' workflows, making it easier for providers and staff to adopt this new approach. Leadership buy-in and staff flexibility also facilitated the implementation of pharyngeal GC TOC procedures into the clinic workflow.

The total time for the clinical provider to perform pharyngeal GC TOC activities—including patient education, specimen collection, and dispensing test kits (where applicable)—was reported to be relatively short, though varied by final case disposition. Sites reported pharyngeal GC TOC visits ranging from 5 to 30 minutes, depending on whether they did in-clinic testing or gave at-home self-collection kits. However, pharyngeal GC TOC-related activities were reported to take up to one hour for a patient with a positive pharyngeal GC TOC. This additional time burden often fell on project staff other than the clinical provider. Reminder calls to patients were reported to be the most time-consuming pharyngeal GC TOC activity, followed by patient education. Some sites mentioned that having a messaging toolkit or other resources, such as text messages and emails, to remind patients of their pharyngeal GC TOC appointments would help decrease the burden on staff. Sites reported the total staffing requirements to implement pharyngeal GC TOC ranged from 3 to 16 individuals (estimated average of 9). In-clinic testing options required more staffing capacity than offering self-collection kits, but this testing method also had a lower completion rate.

Staffing

Sites reported a variety of staff involved in the pharyngeal GC TOC project. Most sites worked with a cross-disciplinary team that included (for example) clinical providers, nurses, clerical staff, and epidemiologists.

- Every site employed clinical providers, who made up most of the team.
- Every site employed a project staff member (e.g., program/research assistant) to conduct visit reminders and follow-ups. Some sites hired a dedicated staff member, while others used existing staff (who may have also had other non-TOC duties) to fulfill this role. Sites did not explicitly mention a difference in feasibility between these two approaches. One site noted that having a disease intervention specialist (DIS) in this role was effective.
- One site highlighted that having a staff member experienced in quality improvement was helpful.

Essential elements of pharyngeal GC TOC implementation that contributed to feasibility included tracking data, linking data and patients prospectively, and keeping track of patients with additional support. Other essential elements included regularly scheduled team meetings focused on making course corrections to implementation and using EHR.

Implementation Facilitators and Challenges

Electronic Health Record Technology

Once pharyngeal GC TOC implementation strategies were up and running, technology was perceived as a significant facilitator for most sites. EHRs proved instrumental in ensuring the data captured were correct and consistent: "The custom templates allowed our site to integrate the pharyngeal GC TOC project into our existing EHR infrastructure. The templates allowed for data capturing and served as a guide for providers and medical assistants by aiding them as they followed the internal pharyngeal GC TOC protocol." Additional functionality, such as tags, queries, and searches, helped clinics identify patients needing pharyngeal GC TOC. At the same time, pop-ups signaled to providers pharyngeal GC TOC requirements, further integrating the intervention into the clinics' respective workflows. The downsides to using EHR systems to identify and track clients include the potential exhaustion of providers and staff resulting from multiple alerts on client records. Upgrades and customizations of EHR systems also can be expensive to implement and maintain.

Client Access

Sites that adopted flexible workflows providing clients different ways to access pharyngeal GC TOC (in-clinic provider or self-collection vs. at-home self-collection) and multiple follow-ups experienced greater success in contacting clients and facilitated pharyngeal GC TOC completion. However, these adaptable workflows sometimes proved burdensome for clinical and administrative staff members. In addition, some of the flexibility offered to clients did not meet their needs. Several sites reported clients coming in person to return self-collection mail-in kits because they could not find a mailbox, while other clients failed to complete pharyngeal GC TOC in the clinic due to transportation issues. Sites noted greater success if they had access to:

- Feedback loops with clients and clinicians (particularly infectious disease specialists) to identify issues and adjust service delivery as needed;
- Experience with the use of at-home self-collection test kits and existing partnerships with a public health laboratory to support at-home self-collection specimens;
- A clinic-based laboratory or appropriate partner (public health vs. a commercial lab) that provided accurate, fast testing and results;
- Dedicated staff to follow-up engagements with clients; and
- Educational materials and wraparound services for clients with limited income, transportation, housing stability, etc.

Leadership and Team Buy-In

Buy-in from partners was considered instrumental. Three sites noted that frequent cross-disciplinary meetings to review workflows and data and strategize adoption helped. A culture of flexibility allowed for rapid pivots during implementation. For example, one site that offered only in-clinic specimen collection noted that it would have been helpful to provide an at-home self-collection test kit option. A clinician at another site that offered multiple collection options reported that patients appreciated being able to select the pharyngeal GC TOC method option that met their needs.

Sites noted that organized patient tracking that identified where they were on the treatment/TOC course facilitated the evaluation process. Still, this activity also required dedicated attention from assigned staff. To be more efficient with staff time, some sites modified their protocol to schedule the pharyngeal GC TOC appointment at the same time as the visit for GC treatment. This eliminated the need for additional staff members to contact the patient to schedule a separate pharyngeal GC TOC appointment.

Other facilitators included having dedicated staff to conduct follow-ups, offering an incentive to patients, scheduling the pharyngeal GC TOC at the clinic visit when the first pharyngeal GC test was performed instead of at the registration desk or during an after-visit phone call, and distributing kits across staff disciplines (as opposed to having the responsibility lie with one point of contact).

Implementation Barriers

Sites underscored three limitations to the pharyngeal GC TOC approach's feasibility within clinical public health practice: effort, relevance, and competition. Several specific barriers included the following:

- **Cost:** Although pharyngeal GC TOC was not deemed a heavy lift within the clinic workflow, sites felt that the costs for a second NAAT test for pharyngeal GC TOC increased laboratory costs, cut into staff time, and taxed appointment availability. As noted previously, additional costs could be incurred in updating EHR functionality. Sites also were concerned that offering multiple testing options would not be cost-efficient in the long term.
- **Low Yield:** In addition, all sites mentioned performing pharyngeal GC TOC for all pharyngeal GC cases may not be worth the effort given the low pharyngeal GC TOC positivity during this project and few treatment failures; most positive pharyngeal GC TOC cases were reinfections or false positives due to residual genetic material.
- **Sustainability:** Two sites reported that because patients could get tested at other local STI clinic sites, they were unsure how to expand or keep this project running. They experienced challenges with transitory patients who may have gotten tested at another site but would like to get treated at their site and vice versa.
- **Challenges in Identifying True Treatment Failures:** The complexity of evaluating the significance of a positive pharyngeal GC TOC was cited as a fundamental challenge. It was not always easy to determine if a positive pharyngeal GC TOC was a treatment failure. In many cases, the suspected treatment failures were due to residual genetic material/false positive, causing some sites to move back the timeline for the pharyngeal GC TOC appointment until at least 14 days after treatment.
- **Data Management:** Several sites reported challenges with collecting data, rendering evaluation challenging and delaying the collection, evaluation, and reporting of data to the CDC. One site stated implementing data collection was a big lift because they needed to incorporate data variables the grant required them to collect into their existing EHR. Another site said their internal EHR was not readily interoperable with REDCap, which they wanted to use to collect pharyngeal GC TOC data. One of the two sites that used Epic, an external EHR system, for pharyngeal GC TOC project data collection mentioned it was harder to flag and use than their internal system. Another site experienced challenges obtaining local Internal Review Board (IRB) approval before the implementation of data collection.
- **Logistics:** Classifying and validating the data concerning where patients received their negative or positive test, as well as patients not showing up for appointments, presented site challenges. Training staff proved cumbersome for some sites, and several reported their providers failing to follow the protocol. Sites that offered at-home self-collection test kit options expected higher uptake of self-collection kits that would have minimized staffing needs; however, many participants preferred in-clinic pharyngeal GC TOC and submitting specimens to the clinic in person. This did not require any changes in processes but was unexpected. Clinics reported that some of these individuals had other symptoms or clinical needs. They sought services simultaneously and thus preferred an in-person pharyngeal GC TOC visit with a medical provider. Sites found the time required to implement pharyngeal GC TOC successfully was high.
- **COVID-19** was also reported as a barrier to implementation since the pandemic disrupted staffing, projects, reassignment, and management and was a strong competing priority for LHDs.

Sustainability

All project sites reported plans to continue pharyngeal GC TOC in some capacity. The two sites that offered multiple collection options will continue offering at-home self-collection kits. Because resources (e.g., staff time) presented a barrier to sustainability, some sites stated they wanted to move pharyngeal GC TOC to their express clinic, where it would be less burdensome to staff. In addition, the low yield of pharyngeal GC TOC to detect treatment failures led sites to underscore that staff resources could be more effectively dedicated elsewhere. Most positive pharyngeal GC TOC cases from all sites proved to be reinfections or false positives.

Sites noted ways they plan to lessen the implementation burden. For example, they will decrease the number of follow-up calls, automated follow-ups, and extracted data elements. Two sites will no longer actively contact patients about pharyngeal GC TOC due to the low yield for detecting treatment failures and the burden on staff time.

In terms of having adequate resources to continue implementation, sites mentioned gaps related to funding, staffing, cost of pharyngeal GC TOC, and implementation guidance. Specifically, funding to support incentives, laboratory costs, and at-home self-collection test kits is needed. Staff support also is required to ease the burdens of case management, specimen collection, and reminder calls. Lastly, a way to continuously extract data would be helpful for continued implementation, as well as a straightforward process map of when pharyngeal GC TOC should be performed and the next steps if there is a suspected treatment failure.

Summary of Key Findings

- Overall, the pharyngeal GC TOC completion rate across project sites was 46%, and pharyngeal GC TOC completion varied by site (range: 36%-71%).
- Sites offering multiple testing options reported that more patients chose in-clinic than at-home self-collection, and the completion rate was higher in-clinic than at-home self-collection.
- Among those with pharyngeal GC TOC performed, 5% (n=39) were positive by GC NAAT.
- The yield of pharyngeal GC TOC to detect treatment failures was low; ceftriaxone treatment failure was rare (n=5; <1%), and there were no cases of cephalosporin-resistant GC detected; most positive pharyngeal GC TOC cases were due to reinfection or false positives.
- In all, implementing pharyngeal GC TOC was feasible for sites. Pharyngeal GC TOC fit in well with the culture of their sites; providers and staff were able to adopt this new approach.
- Leadership buy-in and staff flexibility facilitated the implementation of pharyngeal GC TOC procedures in clinic workflow.
- Sites could adapt methods to extract and report data more efficiently despite the challenges and limitations of EHR systems.
- Staff time and funding pose the biggest threat to sustainability; most sites mentioned they cannot sustain outreach and reminder calls as they are time-consuming. Some sites mentioned they would like to move pharyngeal GC TOC to their express clinic to be less burdensome on staff resources.
- Despite these challenges, all participating sites plan to continue offering at least one testing option for pharyngeal GC TOC.

Appendix

Data Elements

Table 3: Demographic, Behavioral, and Clinical Data Elements Related to Initial Evaluation for Pharyngeal Gonorrhea Episode Managed in Participating STD Clinic

Variable Name	Variable Description/ Question	Type	Null Allowed	Length	Values
TOC1_PATIENTID	Patient ID	Char	No	Up to 18	Character ID. This must be unique per person, up to 18 characters in length, and allow for longitudinal tracking of patients. The Patient ID will be used to link a patient's laboratory results to their epidemiologic data. Note: cannot include any personally identifiable information (PII).
TOC1_EVENTID	Case ID/Event ID	Char	No	Up to 18	Event identifier distinguishes each pharyngeal gonorrhea diagnosis. An Event ID must be established when a patient first tests NAAT positive for pharyngeal gonorrhea. This ID stays the same for the entire pharyngeal gonorrhea event, which includes testing, treatment, and TOC visit(s). This ID can be up to 18 characters in length.
TOC1_SITE	Project site code	Char	No	3	Three-letter abbreviation: DEN= Denver PHX= Maricopa County SFO= San Francisco WDC= Washington D.C.
TOC1_AGE	Age (in years)	Num	No	3	Age in years; 999=Unknown
TOC1_WEIGHT	Weight (in pounds)	Num	No	3	Weight in pounds; 999=Unknown
TOC1_HEIGHT	Height (in inches)	Num	No	3	Height in inches; 999=Unknown
TOC1_SEX	What sex were you assigned at birth, on your original birth certificate?	Char	No	1	1=Male 2=Female 8=Refused 9=I don't know/unknown

TOC1_GENDER	Do you currently describe yourself as male, female, or transgender?	Char	No	1	1=Male 2=Female 3=Transgender 4=None of these/other gender identity 9=Unknown
TOC1_HISPANIC	Hispanic or Latino ethnicity	Char	Yes	1	0= Not Hispanic or Latino, 1= Hispanic or Latino
TOC1_AIAN	American Indian or Alaska Native race	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_ASIAN	Asian race	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_BLACK	Black or African American	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_NHOPI	Native Hawaiian or Other Pacific Islander race	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_WHITE	White race	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_HIV	HIV infection (most current HIV status known at time of initial clinic visit for pharyngeal gonorrhea)	Char	No	1	0= Negative, 1= Positive, 9= Unknown
TOC1_GCHX	Prior history of gonorrhea (ever; per clinical record, self-report and/or per local/state surveillance system)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_GC_Num_12M	If yes: how many gonococcal infections (not including current episode) has the patient had in the past 12 months?	Num	No	3	999= Unknown
TOC1_GC_Num_12M_TX	If patient has had one or more gonococcal infections in the past 12 months (i.e., during the COVID-19 pandemic), was the patient treated with oral cephalosporins for one or more of these episodes?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_GC_Num_12M_TX_oral	If patient did receive ORAL CEPHALOSPORINS for one or more gonococcal episodes in the past 12 months, why?	Char	No	1	1= Needle phobia 2= Clinic did not stock ceftriaxone 3= Ceftriaxone intramuscular injection administration not available due to COVID-19 clinic restrictions 4=Patient refused to return to clinic for treatment 5= Other 9=Unknown

TOC1_ANTIBIOTIC	Did the patient use any antibiotics for any reason during the previous 2 months? (per clinical record or self-report)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_ANTIBIOTIC_TEXT	If yes: please specify (e.g., medication name(s), dose, route, frequency, and duration)	Char	No	100	Free text field
	Gender of sex partners in the past 3 months				
TOC1_CISFEM	Cisgender female partner(s)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_CISMALE	Cisgender male partner(s)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_TRANSFEM	Transgender female partner(s)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_TRANSMALE	Transgender male partner(s)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_UNKFEM	Female partner(s) (cis/trans unknown)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_UNKMALE	Male partner(s) (cis/trans unknown)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_OTH_PARTNER	Other gender partner	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_INITIAL_VISIT_DATE	Initial clinic visit date for pharyngeal gonorrhea episode (i.e., date on which the initial pharyngeal gonococcal specimen was collected)	Date	No	10	MM/DD/YYYY
TOC1_REASON	Reason for initial clinic visit (where initial pharyngeal NAAT performed)	Char	No	1	0= Routine screening 1= Referred as gonorrhea/ other STI contact (e.g., informed by sex partner that they had been exposed to gonorrhea, health department/DIS told them they might have had sex with someone with gonorrhea or other STI) 2= Clinical evaluation for symptoms 3= Referred as gonorrhea/ other STI contact AND clinical evaluation for symptoms 4= Other reason for visit 9= Unknown reason for visit

TOC1_REASON_TEXT	If other reason, please specify	Char	No	100	Free text field
TOC1_NUM_SEX_PARTNERS	How many sex partners ha the patient had in the last 60 to 90 days prior to presenting for pharyngeal gonorrhea clinical evaluation?	Num	No	3	999= Unknown
TOC1_NUM_SEX_INTERVAL	What interview period was used to obtain the patient's number of sex partners?	Char	No	1	1= 60 days (i.e., 2 months) 2= 90 days (i.e., 3 months) 9= Unknown
TOC1_SYMPTOMS	Was the patient experiencing symptoms of urogenital and/ or extragenital gonorrhea at the time of the first clinical evaluation for most recent pharyngeal gonorrhea episode?	Char	No	1	0= No, 1=Yes, 9=Unknown
	If yes: what symptoms were reported?				
TOC1_DISCHARGE	Penile/vaginal discharge	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_DYSURIA	Dysuria	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_SORE_THROAT	Sore throat	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_RECTAL	Rectal bleeding, discharge, and/or pain	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_ABDOMINAL	Abdominal or pelvic pain	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_SWELLING	Testicular swelling or pain	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_OTH_SYMPTOM	Other symptoms (e.g., rash, arthralgias)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_OTH_SYMPTOM_TEXT	If other, please specify	Char	No	100	Free text field
TOC1_DIAGNOSTIC_TEST	What was the initial type of diagnostic test used to diagnose this pharyngeal gonorrhea case?	Char	No	1	1= NAAT 2= Culture 3= NAAT and culture 4= Other 9= Unknown

TOC1_OTH_DIAGNOSTIC_ TEST_TEXT	If other, please specify:	Char	No	100	Free text field
TOC1_NAAT	If NAAT was used, what type of NAAT?	Char	No	1	1= Aptima 2= BD ProbTec 3= Abbott 4= Roche 5= Cepheid GeneXpert 6= Other 9= Unknown
TOC1_OTH_NAAT_TEXT	If other, please specify:	Char	No	100	Free text field
TOC1_GC_CONCURRENT_ SITE	Was gonorrhea diagnosed at other anatomic sites at the time of initial pharyngeal gonorrhea diagnosis (i.e., tests were performed at same clinical encounter)?	Char	No	1	0= No, 1=Yes, 9=Unknown
	If yes: at what anatomic sites were concurrent gonococcal infections diagnosed?				
TOC1_GC_UROGENITAL	Urogenital	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_GC_RECTAL	Rectal	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_GC_OTH	Other	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_GC_OTH_TEXT	If other, please specify	Char	No	100	Free text field
TOC1_TX_PRESCRIBED	Was treatment for gonococcal infection prescribed for current pharyngeal gonorrhea episode?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_TX	If yes: what initial treatment regimen for gonococcal infection was prescribed?	Char	No	1	1= Ceftriaxone 500mg IM ONCE 2= Ceftriaxone 1g IM ONCE 3= Gentamicin 240 mg intramuscularly once PLUS azithromycin 2 gm PO once 4= Cefixime 800mg PO ONCE 5= Other treatment regimen 9= Unknown
TOC1_TX _OTH_TEXT	If other, please specify (e.g., medication name(s), dose, route, frequency, duration)	Char	No	100	Free text field

TOC1_ALTERNATE_TX	If patient did not receive CEFTRIAXONE, why?	Char	No	1	1= Penicillin or cephalosporin allergy 2= Needle phobia 3= Clinic did not stock ceftriaxone 4= Ceftriaxone intramuscular injection administration not available due to COVID-19 clinic restrictions 5=Patient refused to return to clinic for treatment 6= Other 9=Unknown
TOC1_ALTERNATE_TX_TEXT	If other, please specify:	Char	No	100	Free text field
TOC1_INITIAL_TX_DATE	What was the date on which the initial pharyngeal gonococcal treatment regimen was administered?	Date	No	10	MM/DD/YYYY
TOC1_NONGC	Did the patient receive concurrent treatment for additional non-gonococcal bacterial sexually transmitted infection(s) at the time initial pharyngeal gonococcal treatment regimen was administered?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_NONGC_TX	If yes: what treatment for additional non-gonococcal bacterial sexually transmitted infection(s) was prescribed?	Char	No	1	1= Azithromycin 1gm PO ONCE 2= Doxycycline 100mg PO BID for 7 days 3= Moxifloxacin 400mg PO daily for 7 days 4= Azithromycin 1gm PO initial dose followed by 500mg daily for 3 additional days (2.5g total) 5= Doxycycline 100mg PO BID for 14 days 6= Doxycycline 100mg PO BID for 21 days 7= Levofloxacin 500mg PO daily for 10 days 8= Other 9= Unknown
TOC1_NONGC_TX_TEXT	If other, please specify medication name:	Char	No	100	Free text field
TOC1_COMMUNICATION	Was a follow-up communication/contact (e.g., telephone call, text message, email, electronic communication through EMR) from clinic staff/DIS made or attempted to encourage pharyngeal gonorrhea TOC/ follow up visit?	Char	No	1	0=No, 1=Yes, 9=Unknown

	If yes: how was the patient notified to return to clinic for TOC?				
TOC1_REMINDER_CARD	Reminder card provided and/or sent	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_TEXT_MESSAGE	Text message	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_PHONE	Telephone call from project staff	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_EMAIL	Email	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_EMR	Electronic message from EMR	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_OTH_COMMS	Other	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC1_OTH_COMMS_TEXT	If other, please specify	Char	No	100	Free text field
TOC1_NUM_CONTACTS	How many follow-up contacts were made or attempted by project staff to encourage the patient to undergo pharyngeal gonorrhea TOC?	Char	No	1	1= One contact 2= Two contacts 3= Three or more contacts 9= Unknown

Abbreviations: NAAT= nucleic acid amplification test

Table 4: Behavioral and Clinical Data Elements to Be Collected on Pharyngeal Gonorrhea Episode Related to Pharyngeal Gonorrhea Test of Cure

Variable Name	Variable Description/ Question	Type	Null Allowed	Length	Values
TOC2_PATIENTID	Patient ID (non-PII, unique identifier)	Char	No	Up to 18	Character ID. This must be unique per person, up to 18 characters in length, and allow for longitudinal tracking of patients. The Patient ID will be used to link a patient's laboratory results to their epidemiologic data. Note: cannot include any personally identifiable information (PII).
TOC2_EVENTID	Case ID/Event ID	Char	No	Up to 18	Event identifier distinguishes each pharyngeal gonorrhea diagnosis. An Event ID must be established when a patient first tests NAAT positive for pharyngeal gonorrhea. This ID stays the same for the entire pharyngeal gonorrhea event, which includes testing, treatment, and TOC visit(s). This ID can be up to 18 characters in length.
TOC2_SITE	Project site code	Char	No	3	Three-letter abbreviation: DEN= Denver PHX= Maricopa County SFO= San Francisco WDC= Washington D.C.
TOC2_SPEC_COLLECT	Did the patient have a pharyngeal gonorrhea TOC specimen collected?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_SPEC_COLLECT_ METHOD	Was the TOC specimen collected in the clinic or via home testing?	Char	No	1	1= In-clinic self-collect NAAT and/or culture 2= In-clinic clinician-collect NAAT and/or culture 3= Home testing kit 4= Other
TOC2_SPEC_COLLECT_ METHOD_TEXT	If other, please specify:	Char	No	100	Free text field
TOC2_SPEC_COLLECT_DATE	What was the date on which the pharyngeal gonococcal TOC specimen was collected?	Date	No	10	MM/DD/YYYY
TOC2_DIAGNOSTIC_TEST	What was the type of diagnostic test used for pharyngeal gonorrhea TOC?	Char	No	1	1=NAAT 2=Culture 3= NAAT and culture 4=Other 9=Unknown

TOC2_OTH_DIAGNOSTIC_TEST_TEXT	If other, please specify:	Char	No	100	Free text field
TOC2_NAAT	If NAAT was used, what type of NAAT?	Char	No	1	1= Aptima 2= BD ProbTec 3= Abbott 4= Roche 5= Cepheid GeneXpert 6= Other 9= Unknown
TOC2_NAAT_RSLT	Pharyngeal TOC NAAT results	Char	No	1	1= Positive 2= Negative 3= Indeterminant 8= Not performed 9= Unknown
TOC2_CULT_RSLT	Pharyngeal TOC culture results	Char	No	1	1= Positive 2= Negative 3= Indeterminant 8= Not performed 9= Unknown
	IF PHARYNGEAL GONORRHEA TOC WAS POSITIVE (BY NAAT OR CULTURE)				
TOC2_SYMP_IMPROVE	Was there resolution or improvement of presenting urogenital and/or extragenital symptoms within 7 days following initial treatment for most recent pharyngeal gonorrhea episode (if applicable)?	Char	No	1	0= No, 1=Yes, 2= Not applicable, 9=Unknown
TOC2_SEX_ACTIVITY	Has the patient engaged in any type of sexual activity (i.e., oral, genital, anal sex) since the most recent treatment for pharyngeal gonorrhea?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_SYMPTOMS	Was the patient experiencing symptoms of urogenital and/or extragenital gonorrhea at the time of TOC specimen collection?	Char	No	1	0= No, 1=Yes, 9=Unknown
	If yes: what symptoms were reported?				
TOC2_DISCHARGE	Penile/vaginal discharge	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_DYSURIA	Dysuria	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_SORE_THROAT	Sore throat	Char	No	1	0= No, 1=Yes, 9=Unknown

TOC2_RECTAL	Rectal bleeding, discharge, and/or pain	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_ABDOMINAL	Abdominal or pelvic pain	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_SWELLING	Testicular pain or swelling	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_OTH_SYMPTOM	Other (e.g., rash, arthralgias)	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_OTH_SYMPTOM_TEXT	If other, please specify	Char	No	100	Free text field
TOC2_TX_PRESCRIBED	Was treatment for gonococcal infection prescribed for positive pharyngeal gonorrhea TOC result?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_TX	If yes: what treatment regimen for gonococcal infection was prescribed?	Char	No	1	1= Ceftriaxone 500mg IM ONCE 2= Ceftriaxone 1g IM ONCE 3= Gentamicin 240 mg intramuscularly once PLUS azithromycin 2 gm PO once 4= Cefixime 800mg PO ONCE 5= Other treatment regimen 9= Unknown
TOC2_TX_OTH_TEXT	If other treatment regimen, please specify (e.g., medication name(s), dose, route, frequency, and duration)	Char	No	100	Free text field
TOC2_TX_DATE	What was the date on which the gonococcal treatment regimen for the positive pharyngeal TOC was started?	Date	Yes	10	MM/DD/YYYY
TOC2_ ADDTEST	Did the patient have additional testing performed for this pharyngeal gonorrhea episode?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_ ADDTEST_TEXT	If yes: please provide additional testing details (e.g., test type, specimen source, specimen collection date, and test result)	Char	No	100	Free text field
TOC2 _ADDTX	Did the patient receive additional treatment courses for this pharyngeal gonorrhea episode?	Char	No	1	0= No, 1=Yes, 9=Unknown

TOC2 _ADDTX_TEXT	If yes: please provide additional treatment details (e.g., medication name(s), dose, route, frequency, duration, and date started)	Char	No	100	Free text field
TOC2 _DISP	What was the ultimate disposition of the pharyngeal gonorrhea case with positive TOC?	Char	No	1	0=Likely due to reinfection (i.e., reported interval sex) 1=Likely false positive (i.e., residual genetic material post-treatment) 2=Treatment failure after receiving alternate regimen (i.e., did not initially receive CDC-recommended first-line therapy); no evidence of cephalosporin resistance 3=Treatment failure after receiving CDC-recommended first-line therapy; no **evidence of cephalosporin resistance** (i.e., suspected pharmacokinetic/ pharmacodynamic, host factor issues) 4=Treatment failure after receiving CDC-recommended first-line therapy; evidence of cephalosporin resistance (i.e., cephalosporin MIC >0.25 µg/ mL) 5=Other 9=Unknown
TOC2 _OTH_DISP_TEXT	If other disposition, please specify	Char	No	100	Free text field
TOC2 _CDCLAB	Was a positive pharyngeal TOC isolate shipped to CDC lab for additional testing (e.g., antimicrobial susceptibility testing, whole genome sequencing)?	Char	No	1	0= No, 1=Yes, 9=Unknown
TOC2_ CDCLAB_SPECID	If yes: please provide positive TOC specimen ID	Char	No	18	Up to 18 characters
	TOC BEHAVIORAL INFORMATION FOR CASES WITH POSITIVE TOC				
TOC2_SEX_EXCHANGE	Has the patient exchanged money, food/lodging, or drugs for sex in the past 12 months?	Char	No	1	0= No, 1=Yes, 8= Refused to answer, 9=Unknown
TOC2_CONTACT	Was the patient first contacted by sex partner(s) using an escort service, internet sites, or mobile social apps?	Char	No	1	0= No, 1=Yes, 8= Refused to answer, 9=Unknown

TOC2_SEX_TRAVEL	In the past 60 days, has the patient had sex with someone while the patient was traveling outside the United States?	Char	No	1	0= No, 1=Yes, 8= Refused to answer, 9=Unknown
TOC2_SEX_TRAVEL_TEXT	If yes: please specify where (if known)?	Char	No	100	Free text field
TOC2_SEX_SP_TRAVEL	In the past 60 days, has the patient had sex with someone who traveled from outside the United States?	Char	No	1	0= No, 1=Yes, 8= Refused to answer, 9=Unknown
TOC2_SEX_SP_TRAVEL_ TEXT	If yes: please specify where (if known)?	Char	No	100	Free text field
	TOC-RELATED LOGISTICS AND STAFFING				
TOC2_NUM_CLN_VISITS	What was the total number of clinic visits required for this episode of pharyngeal gonorrhea, including all TOC activities?	Num	No	3	999=Unknown

Abbreviations: NAAT= nucleic acid amplification test

Table 5: Laboratory Data Elements for Pharyngeal Gonorrhea TOC Isolates

Variable Name	Variable Description/ Question	Type	Null Allowed	Length	Values
LAB_SPECID	Specimen ID	Char	No	Up to 18	Character ID, up to 18 characters; this must be a unique, site-created ID consisting of 3-character project site code + locally assigned specimen ID (no hyphen or space). Note: Cannot include any personally identifiable information.
LAB_PATIENTID	Patient ID (Non-PII, Unique Identifier)	Char	No	Up to 18	Character ID. This must be unique per person, up to 18 characters in length, and allow for longitudinal tracking of patients. The Patient ID will be used to link a patient's laboratory results to their epidemiologic data. Note: cannot include any personally identifiable information (PII).
LAB_EVENTID	Case ID/Event ID	Char	No	Up to 18	Character ID. Event identifier distinguishes each pharyngeal gonorrhea diagnosis. An Event ID must be established when a patient first tests NAAT positive for pharyngeal gonorrhea. This ID stays the same for the entire pharyngeal gonorrhea event, which includes testing, treatment, and TOC visit(s). This ID can be up to 18 characters in length.
LAB_SITE	Project Site Code	Char	No	3	Three-letter abbreviation: DEN= Denver PHX= Maricopa County SFO= San Francisco WDC= Washington D.C.
LAB_SPEC_COLLECT_DATE	Specimen Collection Date	Date	No	10	MM/DD/YYYY
LAB_SPEC_TYPE	Source of Specimen Collection	Char	No	1	P= pharyngeal
LAB_AGE	Patient Age	Num	No	3	Age in years

LAB_GENDER	Patient Gender	Char	No	1	1=Male 2=Female 3=Transgender 4=None of these/other gender identity 9=Unknown
LAB_AST	Isolate AST Results Available	Char	No	1	0= No (i.e., isolate not viable), 1= Yes, 9= Unknown
LAB_AST_METHOD	Was AST Performed Using Agar Dilution and/or Etest?	Char	No	1	1= Agar dilution, 2= Etest, 3= Both agar dilution and Etest, 9= Unknown
	If AST Performed Using Agar Dilution, Please Indicate Results Below*				
B_LAC	Beta-Lactamase Testing	Char	Yes	1	0= Negative, 1= Positive, 9= Unknown
CFX	Cefixime MIC	Num	Yes	8	0.002, 0.004, 0.008, 0.015, 0.03, 0.06, 0.125, 0.25, 0.50, 1
CRO	Ceftriaxone MIC	Num	Yes	8	0.001, 0.002, 0.004, 0.008, 0.015, 0.03, 0.06, 0.125, 0.25, 0.50, 1
AZI	Azithromycin MIC	Num	Yes	8	0.008, 0.015, 0.03, 0.06, 0.125, 0.25, 0.5, 1, 2, 4, 8, 16
GEN	Gentamycin MIC	Num	Yes	8	0.25,0.5, 1, 2, 4, 8, 16, 32, 64
TET	Tetracycline MIC	Num	Yes	8	0.06, 0.125, 0.25, 0.5, 1, 2, 4, 8, 16, 32, 64
CIP	Ciprofloxacin MIC	Num	Yes	8	0.001, 0.002, 0.004, 0.008, 0.015, 0.03, 0.06, 0.125, 0.25, 0.5, 1, 2, 4, 8, 16, 32
PEN	Penicillin MIC	Num	Yes	8	0.008, 0.015, 0.03, 0.06, 0.125, 0.25, 0.5, 1, 2, 4, 8, 16, 32, 64
	If AST Performed Using Etest, Please Indicate Results Below*				
CFX_ETEST	Cefixime MIC	Num	Yes	8	0.016, 0.032, 0.064, 0.125, 0.25, 0.50, 1, 2, 4, 8, 16, 32, 64, 128, 256
CRO_ETEST	Ceftriaxone MIC	Num	Yes	8	0.002, 0.004, 0.008, 0.016, 0.032, 0.064, 0.125, 0.25, 0.50, 1, 2, 4, 8, 16, 32
AZI_ETEST	Azithromycin MIC	Num	Yes	8	0.016, 0.032, 0.064, 0.125, 0.25, 0.50, 1, 2, 4, 8, 16, 32, 64, 128, 256

LAB_AST_DATE	Date AST Performed	Date	No	10	MM/DD/YYYY
LAB_SHIP_DATE	Date Isolate Shipped to the CDC	Date	Yes	10	MM/DD/YYYY

Abbreviations: AST= antimicrobial susceptibility; MIC= minimum inhibitory concentration
*MIC number should only be recorded [ignore greater than (>) or less than (<) symbols].

Table 6: Aggregate Pharyngeal Gonorrhea Test of Cure Project Participating Clinic Metrics

Variable Name	Variable Description/ Question	Type	Null Allowed	Length	Values
AGG_SITE	Project Site Code	Char	No	3	Three-letter abbreviation: DEN= Denver PHX= Maricopa County SFO= San Francisco WDC= Washington D.C.
AGG_Quarter	Project Quarter of Data Collection	Num	No	1	1= Q1 (5/2021-7/2021) 2= Q2 (8/2021-10/2021) 3= Q3 (11/2021-1/2022) 4= Q4 (2/2022-4/2022)
AGG_Turnaway	Number of Turnaways in the Specialty STD Clinic	Num	No	6	999999= Unknown
AGG_NAAT	Number of Pharyngeal Gonorrhea NAAT Kits Used by Specialty STD Clinic for Pharyngeal Gonorrhea TOC Activities	Num	No	6	999999= Unknown
AGG_Culture	Number of Pharyngeal Gonorrhea Cultures Performed by Specialty STD Clinic for Pharyngeal Gonorrhea TOC Activities	Num	No	6	999999= Unknown
	Total lab costs related to pharyngeal gonorrhea TOC activities				
AGG_NAAT_Cost	Total Cost of NAAT Kits	Num	No	7	9999999= Unknown
AGG_Culture_Cost	Total Cost of N. Gonorrhoeae Culture Materials	Num	No	7	9999999= Unknown
AGG_Etest_Cost	Total Cost of Etest Strips (if applicable)	Num	Yes	7	9999999= Unknown
AGG_Personnel_Cost	Lab Personnel Fees (i.e., personnel engaged in processing TOC laboratory tests)	Num	No	7	9999999= Unknown

Abbreviations: NAAT= nucleic acid amplification test

Citations

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