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

Toolkit

Pharyngeal Gonorrhea Test of Cure (TOC)

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Acknowledgements

The following toolkit has been crafted based on the results 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 pharyngeal 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 selected to demonstrate implementation of pharyngeal GC TOC, including the Public Health Institute at Denver Health (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 Department of Public Health, in San Francisco, CA.

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Stock photos. Posed by models.

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Introduction

NACCHO seeks to improve the health of communities by strengthening and advocating for local health departments (LHDs) and is the only organization dedicated to serving the United States' more than 3,300 local health departments. To this end, NACCHO delivers cutting-edge, skill-building, professional resources and programs, seeking health equity, and supporting effective local public health practices and systems. NACCHO partnered with the CDC's DSTDP in 2021 to galvanize LHD efforts to address the spread of antimicrobial-resistant (AR) GC by implementing routine pharyngeal GC TOC, a new recommendation in the 2021 CDC STI Treatment Guidelines. Pharyngeal GC TOC is intended to mitigate the spread of AR GC by re-testing all who are diagnosed with pharyngeal gonorrhea after they receive recommended treatment to ensure their pharyngeal GC infection is eradicated.

Purpose of This Toolkit

This toolkit shares best practices of pharyngeal GC TOC implementation in STI clinics for clients recently diagnosed with and treated for pharyngeal GC based on the experience of four LHDs. Examples are provided by LHDs demonstrating the implementation strategies for pharyngeal GC TOC in their facility, along with access to tips, tools, and additional resources.

Who Should Use This Toolkit

This toolkit is intended for LHDs and other public health organizations interested in leveraging evidence-based approaches to identify, treat, and ensure the cure of pharyngeal GC infections, particularly among underserved populations.

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. The CDC Reported 710,151 cases nationwide, marking the highest rate of GC incidence since the 1990s, and a more than 28 percent increase in cases since 2017. Historically underserved populations bear a disproportionate burden of increases in GC infections, including gay, bisexual, and other men who have sex with men, transgender persons, sexual minority youth ages 13-24,[1] and Black, Latinx, American Indian/Alaskan Native, and Native Hawaiian/Pacific Islander persons.[1,2]

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.[3,4] Effective and timely treatment of gonococcal infections can prevent adverse health outcomes.

Considered one of the top five AR threat-level pathogens in the U.S., GC's ability to develop antimicrobial resistance has increasingly complicated GC treatment regimens. However, uncomplicated cases of urogenital, anorectal, and pharyngeal GC can be treated with a single dose of ceftriaxone 500mg intramuscularly.[6] 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.[7]

The 2021 CDC STI Treatment Guidelines recommend routine pharyngeal GC TOC with nucleic acid amplification test (NAAT) or culture for any adult or adolescent diagnosed with pharyngeal gonorrhea 7–14 days after initial 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, implementing pharyngeal GC TOC in routine clinical and public health practice has not previously been evaluated.

To address these issues, 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-person clinic visits vs. self-collection test kits).

Four LHDs were selected to implement pharyngeal GC TOC programs, whose demonstration project approach and results are reported below:

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

Results of the Pharyngeal GC TOC Project Demonstration Sites

The four project demonstration sites diagnosed 1,968 pharyngeal GC infections during the study period among 1,783 unique patients. The majority (90 percent) received CDC-recommended first-line treatment with ceftriaxone.[9] Among 1,829 treated cases across the four demonstration sites, the TOC completion rate was 46 percent; the TOC completion rate varied by demonstration site (range: 36 percent – 71 percent). Across all demonstration sites, the median time between treatment and TOC was 14 days (interquartile range: 14–18). Among those with TOC performed, 5 percent (n=39) were positive by NAAT. Of these, 49 percent had pharyngeal GC culture attempted; six positive TOCs (15 percent) were also positive by culture.

The yield of pharyngeal GC TOC to detect treatment failures was low; ceftriaxone treatment failure was rare (n=5; <1 percent), and no cases of cephalosporin-resistant GC were detected. Six positive TOC cases (15 percent) could not be dispositioned due to missing data (i.e., the patient was lost to follow-up).[9]

Pharyngeal Gonorrhea Test of Cure Implementation Strategies

- Customized TOC Electronic Health Record (EHR) Templates and Reports
- REDCap Database for TOC Data Entry and Reports
- Navigators and Other Dedicated TOC Staff
- Multiple Options to Collect Pharyngeal Gonorrhea TOC Specimens:
  - At Home Self-Collection of Pharyngeal Gonorrhea TOC Specimen Kits
  - In-Clinic Self-Collection of Pharyngeal Gonorrhea TOC Specimen
  - In-Clinic Provider Collection of Pharyngeal Gonorrhea TOC Specimen
- Active Follow-Up Calls, Texts, and EHR Messages
- Provision of Incentives to Clients (Gift Cards)
- Leveraging an In-House Laboratory
- Delivery of Multimodal TOC Patient Education
  - In-Person Education
  - Take Home Materials – printed and delivered through EHR

Assessing the Feasibility of Pharyngeal GC TOC for Your Clinic

Below is a **Pharyngeal GC TOC Resource Assessment Checklist** to assess clinic infrastructure and resources considered necessary by participating project sites for pharyngeal GC TOC implementation:

- ☐ What is the burden of pharyngeal GC diagnosed and treated in your clinic annually? Would it be feasible to develop your own clinic-based protocol? Should the clinic refer clients who test positive for pharyngeal GC to a local facility with a pharyngeal GC TOC protocol already in place?
- ☐ What internal partners will you need to engage to facilitate buy-in?
    - ☐ Administrative staff, including front desk personnel, assistants, and others who might be tasked with helping to educate clients about pharyngeal GC TOC and/or calling to remind clients of TOC appointments or alert them of their results.
    - ☐ Clinicians who will need to implement and facilitate pharyngeal GC TOC.
- ☐ Do you have the financial and IT support to adapt your EHR system to create and manage notifications about clients' pharyngeal GC TOC needs?
    - ☐ How will alerts be set up in the system?
    - ☐ How will you mitigate "pop-up fatigue" among clinical staff?
    - ☐ Where will the pharyngeal GC TOC results be provided? Will clients have to access them from the laboratory directly, or will your clinic be able to update your EHR system to provide the test results directly in the client's medical record? (Is your clinic set up to allow clients to access their medical records online?)
- ☐ What is your clinic's current pharyngeal GC testing capacity?
    - ☐ Will tests be processed onsite or through a clinical or public health laboratory?
    - ☐ How will clients access their results?
    - ☐ How will you manage the costs of additional testing?
    - ☐ If you allow self-collection of specimens offsite, does your community have the capacity to facilitate mail-in tests to your clinic or laboratory facility? (That is, are mailboxes or postal services easily accessible/available?) If not, will your clinic be able to handle specimen drop-off and processing, particularly if you do not have an onsite clinic?
- ☐ Who will be responsible for educating clients about pharyngeal GC TOC? Who will contact them about upcoming/missed TOC appointments? Who will alert them about their results?
- ☐ How will your clinic handle the additional clinical/appointment time required to facilitate pharyngeal GC TOC?
- ☐ What additional staff must be hired and/or trained to facilitate pharyngeal GC TOC activities?
- ☐ How will staff be trained in educating clients and facilitating pharyngeal GC TOC?
- ☐ Do you have adequately trained staff on board to collect and manage data collection, report results as appropriate to the health department, and conduct and report on the evaluation of staff and client satisfaction and experience?

Overall General Approach to Pharyngeal GC TOC

The following pharyngeal GC TOC workflow draws on the 2021 CDC STI Treatment Guidelines and the approaches demonstrated by the pharyngeal GC TOC project sites. A general approach to pharyngeal GC TOC implementation in clinics involves the following steps:

1. Clinical staff recruit patients for pharyngeal GC TOC through several mechanisms:
    - At the time of a positive pharyngeal GC test,
    - After a positive test, after being flagged in the EHR system, or
    - Schedule the TOC appointment at the same time as or immediately after treatment
2. At that time, clinicians educate clients about pharyngeal GC TOC, which generally involves having a pharyngeal GC NAAT performed with or without culture to ensure the infection is eradicated. They then educate clients about the pharyngeal GC TOC specimen collection process, which often involves one of the following:
    - Specimen collection by clinic staff: Clinical staff collect the specimen from clients and send it off for testing.
    - Self-collected specimen collection onsite (at the clinic or laboratory testing site): Clients use the kit provided to them and return it as directed.
    - Self-collected specimen offsite (at home): Clients use the kit provided at the clinic or through the mail and return their specimen for testing at the clinic or to the testing site via mail or in-person.
3. Clinicians call or send clients a reminder in the EHR system about their need to submit a specimen for pharyngeal GC TOC the day before it is due.
4. Clients who fail to respond to alerts from clinicians receive a follow-up reminder.
5. Upon submission of their pharyngeal GC TOC NAAT testing, clinical staff receive a notification in the EHR system, prompting them to monitor the results, alert patients of their results, and notify patients where they can access them.
6. If there is a positive pharyngeal GC TOC NAAT test, clinical staff coordinate evaluation with a site medical director, coordinate care network (CCN) representative, or subject matter expert to determine if treatment failure occurred, indicating a need for partner referrals and re-treatment. Repeat pharyngeal GC NAAT and GC culture is often conducted, even when a false positive is suspected.
7. If the pharyngeal GC TOC culture is positive and antimicrobial susceptibility testing (AST) is performed, clinics can assess whether the GC isolate has reduced susceptibility (RS) to ceftriaxone. The results of pharyngeal GC culture and susceptibility testing can determine the next steps in evaluating and managing the positive pharyngeal GC TOC and public health response.
8. The public health lab should be notifed if there is evidence of antimicrobial resistance in a pharyngeal GC TOC isolate. Depending on the local protocol and the lab conducting the culture and AST, the public health lab may be the one to notify the clinic team that a GC isolate has AST results concerning for cephalosporin-resistant GC.

Logistical Considerations and Lessons Learned for Pharyngeal GC TOC

There are some logistical factors to consider before pharyngeal GC TOC implementation, including:

- Developing clear protocols that reflect the needs of clients and staff and enhance (rather than impede) existing processes
- Securing buy-in from the leadership team and ensure all staff receive adequate training
- Maximizing existing resources, notably the clinic's electronic health record (EHR) infrastructure, to track patient appointments and outcomes
- Planning for evaluations of client and staff experiences and satisfaction to assess the performance of pharyngeal GC TOC and make recommendations to enhance its facilitation

Below are some specific factors to keep in mind:

Pharyngeal GC Specimen Collection

Pharyngeal GC TOC can be conducted by clinicians or individually by the clients themselves. Depending on the clinic's capacity, collected pharyngeal GC specimens can be assessed in-house or sent to a commercial or public health laboratory.

Who Should Receive Pharyngeal GC TOC

Clinics should recommend pharyngeal GC TOC to all clients diagnosed with and treated for pharyngeal gonorrhea.

Recruitment of Clients into Pharyngeal GC TOC

Clinics should integrate pharyngeal GC TOC into their general protocol. Alerts can be added to the EHR system, reminding clinical staff about the following:

- Clients who have tested positive for pharyngeal GC and need to be educated about pharyngeal GC TOC,
- Clients who need to be contacted to complete their pharyngeal GC TOC, and
- Clients whose pharyngeal GC TOC results have been received.

To encourage the uptake of pharyngeal GC TOC, clinics should provide:

- Educational materials, preferably in the primary language(s) spoken by clients, both in print and online. In-person instruction and clarification coupled with additional videos and downloadable information sheets can be beneficial.
- Explicit instruction on how to submit tests (if enabling self-testing) and access results. This will be particularly important if you require clients to send their tests directly to the laboratory or are not equipped to provide test results.
- Gift cards and travel vouchers to incentivize follow-through of pharyngeal GC TOC.

Clinical Challenges

Pharyngeal GC TOC can create some challenges. Among clients that had TOC performed, demonstration sites reported low pharyngeal GC TOC yield for identifying treatment failures within the client population, despite requiring significant local resources:

- Demonstration sites found that most positive pharyngeal GC TOC cases were re-infections or false positives due to residual genetic material. To reduce false positive test results, demonstration sites revised their local protocols during the project period to recommend pharyngeal GC TOC at least 10 days post-treatment.
- Sites also noted that partnerships with clinics already implementing pharyngeal GC TOC could help consolidate care locally, providing a place where clients can be referred through warm handoffs for pharyngeal GC TOC following pharyngeal GC treatment.

Appointments and Specimen Collection

The demonstration sites for the project overall did not find that pharyngeal GC TOC represented a heavy lift to implement and incorporate into their clinical workflow. They did note, however, that pharyngeal GC TOC did involve some unexpected costs:

- Pharyngeal GC TOC requires clients to engage in additional and more extended appointments due to patient education requirements and specimen collection when conducted in the clinic (either by the provider or the client via self-collection). Some clinics noted that pharyngeal GC TOC could increase appointments by an average of 30-60 minutes. To mitigate this challenge, demonstration sites recommended scheduling the pharyngeal GC TOC appointments simultaneously or immediately before or after treatment. This approach helped increase the likelihood of patients returning for their subsequent pharyngeal GC TOC appointments.
- A positive pharyngeal GC TOC result requires further evaluation with follow-up testing, which can increase the demands on laboratory partners and testing costs, both in the clinic and offsite. Demonstration sites did note, however, that having a public health laboratory is not necessary for pharyngeal GC TOC; commercial diagnostic providers were capable of facilitating these services.
- Clinics that enable clients to collect at-home specimens require additional educational support for clients who will need to know where to return their specimens and how to access their results. One demonstration site noted that clients initially had trouble using home testing kits since the results were available only from the testing kit's laboratory. Clients were accustomed to accessing results through their online medical record with the demonstration site. The demonstration site eventually updated the reporting procedure for home kits, enabling clients to see their results directly in their online medical records; however, until that modification, staff had to help clients access their results from the testing kit's laboratory. Some patients forgot to provide their collection date or identifiers on the specimen, creating challenges to validate the specimen.
- Demonstration sites initially thought clients would prefer at-home*specimen collection. However, for sites that offered both in-clinic and non-clinic specimen collection, most clients chose in-clinic collection (either through self-collection or clinician-performed).
- Sites noted that mail-in collection kits often proved burdensome for clients who had trouble finding local postal services, including mailboxes, to return their specimens. Many clients returned their home collection specimens to the clinic in person, which could be challenging for staff, particularly if the specimen needed to be returned to an offsite laboratory service. As a result, sites tended to favor in-clinic specimen collection (whether by provider or client) when possible, since it seemed most cost-efficient in the long term. Other sites made appointments for clients at a laboratory site.

*The use of at home self-collection kits for pharyngeal GC TOC has not been FDA approved.

EHR System

Demonstration sites indicated that an appropriately customized EHR system was essential to effectively implementing pharyngeal GC TOC within a clinic. Some strategies included the following:

- Sites set up appropriate alerts for providers that indicated which patients had a recent positive pharyngeal GC test and completed treatment, upcoming pharyngeal GC TOC appointments, and pharyngeal GC TOC results.
- Sites warned against collecting pharyngeal GC TOC data through non-EHR mechanisms like REDCap, since these platforms may not be readily integrated with client records and require additional tailoring and data entry to be useful.
- EHR systems needed to be adequately integrated with online patient portals that enabled clients to access test results and provided them with notes about the next steps regarding the pharyngeal GC TOC process.
- EHR systems must be set up with clear templates leveraging smart tags and text, phrases, and other elements to help track and generate lists of persons eligible and engaged in pharyngeal GC TOC. Using customizable templates within the EHR system can help integrate the pharyngeal GC TOC intervention seamlessly into the provider's workflow, ensuring efficiency and accuracy in data collection.
- In creating forms for the EHR system, demonstration sites cautioned against requesting too many additional variables. Instead, they recommended asking only for the information required, using uniform answers that providers can readily select from checklists. Open, fillable fields can result in non-uniform responses for providers to wade through, potentially undermining care and slowing down appointments.
- Demonstration sites cautioned against overuse of auto alerts about pharyngeal GC TOC issues, since providers may experience “pop-up fatigue” and be inclined to close out the notifications.

Educational Materials for Providers and Clients

Demonstration sites found that educational materials were imperative for clients and clinicians alike, with staff training considered essential to ensure buy-in and program fidelity:

- Clients appreciated having additional printed and electronic supplemental educational materials, including brochures, videos, and tear sheets. Sites provided these materials in both English and the client’s primary language(s), along with their after-visit summary, in their online accessible patient record.
- Providers noted that the educational materials provided with the testing kits could be leveraged, reducing production costs.
- Rather than handing these materials to clients, demonstration sites stressed it was best to review the materials (through demonstration) with the clients directly. This review could be facilitated by the clinicians themselves or another trained staff person.
- Demonstration sites also recommended creating job aids, including standard operating procedures, tip sheets, and a toolkit, to help clinicians and other staff facilitate the pharyngeal GC TOC process. Implementation and refresher trainings and grand rounds reviewing cases held regularly by pharyngeal GC TOC leaders can help ensure that the pharyngeal GC TOC process operates appropriately. Moreover, thoughtful training was considered essential to ensuring buy-in and successful implementation.
- Staff should have access to a list of websites and/or webinars that provide information and training useful for implementing pharyngeal GC TOC.

Staffing Capacity Requirements

Demonstration sites recommended an interdisciplinary team to facilitate pharyngeal GC TOC. Assembling and training this team represented an essential piece of the program's initial implementation, with elements becoming less burdensome as it became increasingly routinized in the staff structure.

Most sites worked with a cross-disciplinary team that included the following:

- *Clinical Providers*, including physicians and nursing staff, provided direct health services to clients, counseling and recommending them for pharyngeal GC TOC, and assisting with follow-up of suspected treatment failures. They are essential to delivering education, ensuring client buy-in, interpreting test results, providing treatment recommendations, and consulting on suspected treatment failure case management.
- *Administrative Staff* provided much needed support in scheduling and following-up with clients about their appointments.
- *Navigation Staff*, including program/research assistants, proved essential to helping clients navigate visits and testing. One site hired a disease intervention specialist (DIS), who is trained in intervention protocols, to confer with clients about next steps and continued engagement with pharyngeal GC TOC. Some demonstration sites hired a dedicated staff member for this role. In contrast, others divided the responsibilities for client management and follow-up among existing employees and their non-TOC duties.
- *Peer Navigators* were leveraged to ensure cultural and linguistic alignment and support in engaging and providing client follow-through with pharyngeal GC TOC.
- *Evaluators* were also cited as essential to collecting, managing, analyzing, and reporting data to staff and local health department officials, as necessary. Evaluators can help highlight successes and inefficiencies in a clinic's pharyngeal GC TOC protocol. Indeed, they are instrumental in ensuring quality improvement; designing and disseminating surveys assessing client and provider experience would help determine areas working well in the pharyngeal GC TOC protocol; and where additional modification is required.
- *External Partners*
    - *IT Provider/Web Developer*: Having a solid relationship with your organization's IT provider and/or web developer can facilitate updating the EHR system, which demonstration sites indicated was core to implementing pharyngeal GC TOC.
    - *Laboratory*: For sites that do not have an onsite laboratory, having an established lab partner is integral to facilitating pharyngeal GC TOC. Determining which laboratory to partner with may depend on site specimen collection protocols (e.g, in-clinic self-collection, clinician-only specimen collection, offsite self-collection) and existing clinical infrastructure/capacity. Also, it is essential that laboratory results can be automatically added to client records, rather than referred only to clinical and office staff, which can prove administratively burdensome.

Promoting Sustainability

All demonstration sites intend to continue pharyngeal GC TOC in some form moving forward. Essential elements that contribute to the ongoing successful feasibility and sustainability of pharyngeal GC TOC include:

- Conducting formative research before implementation to understand an organization's client populations, including their linguistic, cultural, and clinical needs. Without this grounding, the pharyngeal GC TOC intervention implemented may not align with the client's reality, undermining its uptake and effectiveness.
- Creating a checklist or toolkit for implementing the program can help guide the process and ensure its successful integration into the clinic's existing systems.

- Meeting regularly with your pharyngeal GC TOC team to review client engagement and identify course corrections to implementation.
- Leveraging EHR data collection to generate prospective tracking of clients in the system, facilitating identification of pain points in the pharyngeal GC TOC workflow.
- Conducting patient surveys to gather feedback on client satisfaction with the pharyngeal GC TOC process and understand why they did or did not move forward with testing.
- Polling clinical staff to understand what works well and what needs improvement in facilitating the pharyngeal GC TOC.

GC TOC in Action: A Deeper Look

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 EHR'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. DSHC 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 re-treatment directed by the medical director. If a client with pharyngeal GC had an isolate with reduced susceptibility (RS) to ceftriaxone, the SURRG ARGC TOC process was used.

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

1. SURRG nurse monitored 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 facilitated an in-clinic laboratory-only visit (SURRG nurse placed a future lab order) 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.

Feasibility of implementation and impact on clinic capacity involved estimating the time/cost needed for different pharyngeal GC TOC activities. 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.

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.

Additional Resources

CDC. Update to CDC's treatment guidelines for Gonococcal infection, 2020. MMWR. 2020;69(50): 1911–1916. https://www.cdc.gov/mmwr/volumes/69/wr/mm6950a6.htm

CDC. STI Treatment Guidelines: 2021 Recommendations Available: https://www.cdc.gov/std/treatment-guidelines/default.htm

Citations

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