REQUEST FOR APPLICATIONS

PILOTING SELF-SPECIMEN COLLECTION OUTSIDE OF CLINICAL SETTINGS USING A TELEMEDICINE MODEL FOR TESTING FOR GONORRHEA & CHLAMYDIA

National Association of County and City Health Officials (NACCHO)

Release Date: October 13, 2020

Due Date: November 25, 2020

For questions about the Request for Applications (RFA), contact Rebekah Horowitz, Senior Program Analyst, HIV, STI, & Viral Hepatitis, at rhorowitz@naccho.org.

I. Overview

The National Association of County and City Health Officials (NACCHO) represents the nation's nearly 3,000 local health departments (LHDs), which work to protect and improve the health of all people and all communities. NACCHO's HIV, STI, and Viral Hepatitis program aims to strengthen the capacity of LHDs to prevent, control, and manage HIV, STIs, and hepatitis in their communities. NACCHO supports these efforts by providing technical and capacity building assistance, developing and disseminating tools and resources, facilitating peer information exchange, and providing learning opportunities.

Physical distancing and stay-at-home orders adopted at the national, state, and local levels to control COVID-19 have changed the STD healthcare landscape in 2020. Amidst the pandemic, STD programs are exploring innovative approaches to maintain access to high-quality STD care without having patients physically come into STD clinics—this includes patient self-collection of specimens outside of clinic settings. To establish models of practice, NACCHO, with support from the Centers for Disease Control and Prevention (CDC) Division of STD Prevention (DSTDP), will fund 1–2 LHDs up to $300,000 to design, pilot, and evaluate implementation of a telemedicine model that offers patients the option to self-collect gonorrhea and chlamydia specimens outside of the clinic setting (e.g., at home) and mail-in the specimens to a public health laboratory for nucleic acid amplification testing (NAAT). This project will provide essential information about the development of a telemedicine model that offers specimen self-collection to targeted STD patients, the feasibility of patient self-collection of specimens outside of clinic settings to maintain access to laboratory testing (via public health laboratory), timing of testing turnaround and result delivery to evaluate timeliness of treatment and other disease management, and assess patient characteristics and satisfaction with the approach. Findings will be shared broadly with STD programs across the country.

II. Problem Statement

Chlamydia trachomatis and Neisseria gonorrhoeae are the two most common notifiable diseases in the United States. In 2018, nearly 1.8 million cases of *C. trachomatis* infection and over 500,000 cases reported of *N. gonorrhoeae* infection were reported. Untreated chlamydial and gonococcal infections can cause serious sequelae including pelvic inflammatory disease, ectopic pregnancy, and infertility, and in the case of *N. gonorrhoeae*, disseminated gonococcal infection and heightened risk of HIV acquisition and transmission.

Need for Innovative Testing Approaches

Diagnosing chlamydia and gonorrhea without laboratory testing can be challenging. Chlamydial and gonococcal infections, especially when at the cervix or non-genital anatomic sites, are frequently asymptomatic. Additionally, classic signs and symptoms of these STDs, such as vaginal or urethral discharge, can be caused by other microorganisms.

Without a means to diagnose chlamydia or gonorrhea, healthcare providers often resort to syndromic management, in which patients are treated for syndromes (such as urethral

discharge) based on likely microbial causes. Syndromic management may lead to both overuse of antibiotics and under treatment of the microorganism causing the symptoms.

With the COVID-19 pandemic leading to widespread STD clinic closures, some STD programs have rapidly implemented innovative telehealth approaches but access to diagnostic STD laboratory testing has proven challenging. Patient self-collection of specimens outside of clinic settings (i.e., at home) may expand access to STD testing especially during widespread clinic closures.

Laboratories can validate and offer chlamydia and gonorrhea testing of at-home self-collected specimens, including rectal and pharyngeal swabs. Some of the laboratories can bill insurance for the tests; however, insurance reimbursement may not cover the costs of shipping and any wrap-around services. Therefore, the out-of-pocket costs for testing packages (often >$100) at commercial laboratories is unlikely to be affordable for low-income and underinsured populations. Also, a telehealth component may help ensure the right individuals are tested per the USPSTF and CDC guidelines.

III. Objectives

The objectives of this project are to:

- Design and pilot a telemedicine model to offer asymptomatic patients the option to self-collect gonorrhea and chlamydia specimens outside of clinic settings.
- Assess the feasibility of patient self-collection of specimens outside of clinic settings for *C. trachomatis* and *N. gonorrhoeae* testing, including kit orders, kit return rate, GC/CT positivity, and characteristics of patients tested and treated.
- Collaborate with local or state public health laboratory to establish necessary workflows and support testing and resulting. Assess timing of testing turnaround from specimen postage date (i.e., when program/laboratory sends specimen collection kit) to test result returned to telehealth provider and patient to evaluate timeliness of testing and case detection.
- Assess the timeliness of treatment from date the telehealth provider receives the positive result and the patient is treated.
- Assess percent of persons tested who meet the USPSTF and CDC screening recommendations/guidelines or who need a repeat 3-month test or who are PrEP clients needing frequent STD screening.
- Assess patient satisfaction with the approach, including motives for accepting and/or refusing self-collection option.
- Assess willingness to participate again and/ or assess acceptability and return rates for second testing orders at 3 months for those treated for CT/GC and PrEP users, as recommended by CDC.

This is a program improvement and evaluation effort to identify replicable models and best practices for patient self-collection of specimens outside of clinic settings and testing of specimens for patients recommended by the USPSTF or CDC treatment guidelines.

IV. Requirements

This funding is open to all jurisdictions that have a GISP funded clinic with capacity to do CT/GC NAATs and GC culture in the clinic and has on-site treatment. Experience with telemedicine and self-collected CT/GC NAATS in the clinic and experience with program evaluation including collection of cost data are desirable.

The jurisdiction must have the organizational and project management capacity over the project period to design and implement a telemedicine model that offers patient self-collection of specimens outside of clinic settings, including the capacity to identify and reach appropriate populations at elevated risk of chlamydia and/or gonorrhea. Program activities will include: (1) identifying persons with elevated risk of STDs who would benefit from screening per USPSTF and CDC recommendations/guidelines (examples include: sexually active women <25 years of age, those living with HIV, or MSM); persons recently diagnosed within gonorrhea or chlamydia and require re-testing three months after treatment; and persons receiving HIV pre-exposure prophylaxis; (2) design a telemedicine model to triage patients who would benefit from testing, including designation or hiring of an appropriate staff member (e.g. RN) to manage telemedicine triage; (3) efficiently and safely providing specimen collection kits by the participating laboratory to patients; (4) providing high-quality guidance to participating patients on specimen collection, handling, packaging, and shipping, and who patients should contact if they have questions by the telemedicine provider; (5) developing streamlined processes for specimen handling and transport to the laboratory; (6) ability to receive electronic laboratory results from participating public health laboratory to the telehealth system; (7) ensuring the return of test results to patients; and (8) ensuring timely treatment of persons diagnosed with chlamydia or gonorrhea.

Use of **telehealth/telemedicine** digital health platforms is strongly encouraged.

Jurisdictions will have flexibility in how project approaches are designed and are encouraged to propose and apply approaches that are sustainable and can be expanded (scalable). Jurisdictions may also consider innovative approaches to challenging issues, such logistics and third-party/healthcare insurance reimbursement.

The clinic must work with APHL and/or CDC to identify at least one partnering local or state public health laboratory within the jurisdiction (requirements described below). As part of project development following the award, the clinic and laboratory will work with CDC to establish a protocol for validation, if needed, submission, and return of results. The clinic should identify a person or entity that will receive test results from the laboratory. The jurisdiction will then be responsible for returning results to the patient and ensuring treatment and any appropriate follow-up.

The clinic and laboratory must have the capacity to execute the program strategies and activities and demonstrate the ability to meet the project period outcomes.

An appropriate local health department/project GISP site and laboratory should have, at minimum, the below features:

- Health department leadership committed to implementing program strategies outlined in this RFA.
- STD clinic staff with the capacity and commitment to develop and follow local protocols for: (1) providing telemedicine to triage the right patients to self-collected tests outside of a clinic settings; (2) efficiently providing specimen collection kits to up to 1000 females <25 years of age (one swab/female) and 1000 MSM (three swabs/MSM) patients as well as patients that need 3 month testing after treatment for CT/GC and PrEP users to test for chlamydia or gonorrhea (urine and pharyngeal, vaginal, and rectal swabs) per USPSTF and CDC guidelines; (3) providing high-quality guidance and educational materials to provide with the collection kits/material to participating patients; (4) developing streamlined processes for specimen distribution, handling, and transport to the laboratory; (5) ensuring treatment and appropriate follow-up of persons diagnosed with chlamydia or gonorrhea, and (6) evaluating the program including factors associated with success in testing and treatment and costs of the program to detect and treat an infected person.
- In collaboration with CDC and APHL, ability to identify and work with a public health laboratory within the jurisdiction or state with the capacity and commitment to: (1) perform NAAT for *C. trachomatis* and *N. gonorrhoeae* on up to (4,000) such specimens, (2) validate *C. trachomatis* and *N. gonorrhoeae* NAAT protocols for specimens collected by patients in non-clinic settings (laboratories with validations that are complete or in process are preferred), (3) can use or easily adapt existing systems for return of results to the telehealth provider and the client and for reporting of positive test results to the state/local HD, and (4) transport anonymized, remnant NAAT specimens to the CDC-DSTDP/Laboratory Reference and Research Branch (LRRB) for creation of a specimen bank to help other laboratories with future validations, for evaluation of molecular markers for ARGC or for research applications to develop new tests. LRRB can provide technical assistance for validation of testing specimens collected by patients in non-clinic settings. Using the local PHL within their jurisdiction is desirable.
    - Nucleic acid amplification testing of patient self-collected specimens collected outside of clinical settings is not FDA-cleared and is considered a laboratory-developed test (LDT). LDTs must be validated such that every methodologic step of its use that differs from the 510(k) cleared/premarket approval (PMA) cleared version of the same test must be validated under the review of their relevant Clinical Laboratory Improvement Amendments (CLIA) authority or equivalent authority.
- A gonorrhea case count in the local health department jurisdiction of at least 750 cases per year and at least 250 cases in the clinic per year. Jurisdictions must identify in writing, as part of the funding application, the number of chlamydia and gonococcal infection diagnosed in the jurisdiction's STD specialty clinic(s) in 2018 and 2019.
- Ability to include young women <25 years and MSM, as indicated by local protocols, for self-collection of pharyngeal, rectal, vaginal, and/or urine specimens. Ability to include PrEP users is highly desirable and to do so clinic should also be offering PrEP in the clinic.

- A designated staff member in an STD clinic or health department STD program who will manage the program, provide oversight and QA of data collection and follow-up with every person in the program with negative results and actively follow-up with those who tests positive for chlamydia or gonorrhea and link to treatment and other services as needed.
- Ability and willingness to provide CDC-DSTDP and NACCHO with regular project updates and performance metrics (including number of kits distributed, number of tests performed, test positivity, number of patients successfully treated, and basic demographic data about patients and their satisfaction with the approach) and a comprehensive final project summary.

V. Funding and timeframe

Selected LHDs will be awarded $150,00 – $300,000 (depending on the number of sites awarded) to design, pilot, and evaluate a telemedicine model offering self-collection for *C. trachomatis* and *N. gonorrhoeae* to STD patients outside of clinic settings. The selection of sites will be determined through demonstrated background need, site capacity as described in their application, and feasibility of the proposed approach.

Funding should be used to support costs for clinic personnel (RN, DIS, project manager), identifying patients, educational materials, IT equipment and telemedicine platform, patient follow-up regarding test result and linkage to treatment, if positive, and contractual support for EHR, telemedicine and surveillance systems enhancements. Funds may be used to support a full-time employee with the organizational capacity to conduct and oversee program activities. All funding should support patient self-collected specimen collection and testing activities.

KEY DATES

Event	Date
RFA Release	October 13, 2020
Application Submission Deadline	November 25, 2020
Telephone Interviews with Finalists (if needed)	Early December 2020
Anticipated Award Notification	Mid-December 2020
Anticipated Contract Execution	January 2021
Implementation and Evaluation Period	(one year)
Dissemination of lessons learned	(after project period)

VI. Eligibility and Contract Terms

Eligible applicants include LHDs with a GISP clinic and that are active NACCHO members. To confirm membership status, or to become a dues-paying NACCHO member, visit http://www.naccho.org/membership. See the Requirements section on page 4 for additional information about eligibility.

Applicants should plan for approximately 6 months of project implementation. Projects will begin on the date of contract execution. Please note that NACCHO reserves the right to make changes to the project timeline and payment schedule if necessary.

Agreement with NACCHO's standard contract terms and conditions is a requirement. **No modifications to the terms or contract language will be made. Jurisdiction that cannot agree to NACCHO's contract language should not apply for this initiative.** Read the standard contract language for more information. As part of the application, the contractor/organization will be asked to verify that they have read NACCHO's standard contract language and have provided a copy to the individual with signing authority at your organization for advanced consideration. It is the responsibility of the selected site to return a signed copy of the contract no later than December 31, 2020. NACCHO has a specific contract template as approved by the State's General Counsel for applicants from State of FL and TX. Please email us for a copy should you need it.

Selected applicants will enter a contract with NACCHO to complete the deliverables specified in the application. NACCHO will issue awards in the form of a Fixed Price Contract and pay each awarded Applicant in exchange for completion of the assigned scope of work and accepted deliverables.

Deliverables may be priced as a percentage of the total award amount. NACCHO will provide a payment schedule in accordance with the assigned completion percentage (estimated 3-4 payments). Please note: NACCHO reserves the right to make changes to the project timeline and payment schedule if necessary.

A finalized scope of work will be agreed upon following selection.

VII. Proposal Format

The application should be single-spaced and use Times New Roman 12-point font, not to exceed eight (8) pages in length, and should include the following sections:

A. Cover page

Provide a cover sheet that includes the applicant's contact information.

B. Background and Need (~2 pages)

a. Describe your site population including an overview of your service area and community, number and socio-demographic description of clients seen/tested annually in local STD clinic(s), (pre-COVID and currently) and describe clinic changes made since COVID (reduce hours, staff, provide only essential services (define - e.g., symptoms, contacts to STDs)).

b. Provide the chlamydia and gonorrhea case counts and positivity rates overall and among important populations (e.g., adolescents, racial/ethnic minorities, and sexual and/or gender minorities) for 2018 and 2019 and if you have it data during COVID; provide data on the anatomic site distribution of chlamydia and gonorrhea.

C. Capacity to Implement Project (~3 pages)

a. Describe how you propose to accomplish project objectives and which patient population(s) may be included.

b. Specifically describe how you currently test for *C. trachomatis* and *N. gonorrhoeae*, including the test platform used (e.g., Aptima, Cepheid, etc.). Also,

describe the laboratory currently providing this service and if they are willing to participate in the demo project and validate and run ~4,000 specimens self-collected outside the clinic setting.

i. Include a letter of support/intent to participate from the laboratory. In the letter of intent, please describe the status of a validation plan for testing self-collected specimens in a non-clinic setting. If the laboratory has not already completed a validation plan, please indicate the amount of time needed to do so.

c. What is your experience with managing and implementing special clinical evaluation projects?

i. Describe your experience with conducting and evaluating projects. How might you go about offering both men and women the opportunity for self-collection of samples in non-clinic settings?

ii. Describe your experience providing educational materials and guidance to men and women with STDs, especially those with low health literacy. How might you ensure that enrollees have and understand appropriate information on self-collection and specimen handling?

iii. Describe your experience and current capacity to develop and follow project protocols related to effectively collecting, handling, testing, and transporting of NAAT specimens, and ensuring treatment of persons diagnosed with chlamydia or gonorrhea.

iv. Describe your experience and capacity to collect and locally manage project data, such as the demographics of those tested, specimen tracking, test results, test turn-around time, and quantitative and qualitative data on project facilitators and barriers.

v. Describe your experience with in-clinic self-collection of CT/GC NAAT specimens.

vi. Describe your experience with telehealth and/or telemedicine services in your clinic.

D. Key Staff and Partners (~2 pages)

a. Proposed key staff to manage the project overall, their role, and relevant experience.

b. Proposed key staff to implement the project, their role, and relevant experience.

c. Proposed key staff to evaluate the project, their role, and relevant experience.

d. Description and relationship to any partners critical to implementing the innovation or improvement.

i. Include letter(s) of support from critical partners in addition to the laboratory letter of support, such as the medical director of the clinic (as an attachment)

e. Description and relationship to any partners critical to evaluating the innovation or improvement.

E. Attachments - Required

a. Proposed budget, with justification

b. Anticipated workplan

c. Vendor Information Form
d. Certification of Non-Debarment
e. W-9
f. FFATA data collection form

F. Attachments – Optional

a. Resumes/CVs of Key Staff
b. Letters of support from any key partners critical to the project

Attachments will not count against the total page limit. All pages, charts, figures, tables, and any additional information/attachments should be numbered.

VIII. Selection Criteria

NACCHO and CDC DSTDP will review and score applications for this RFA in accordance with the following criteria (out of 100 points):

- Evidence of chlamydia burden (10 points)
- Evidence of gonorrhea burden (20 points)
- Jurisdictional Capacity (50 points) to implement the project including any experience with self-collected GC/CT NAATS specimens, telehealth/telemedicine services, express visits, development of culturally sensitive educational materials at low literacy levels, and data collection and program evaluation.
- Amount and relevant experience of key staff or partners responsible for carrying out project activities (20 points)

NACCHO-DSTDP may conduct telephone interviews with finalists. Interviews would be conducted in early December 2020.

NACCHO standard contract language can be found here, if necessary.

IX. Submission Instructions

The deadline to submit applications is November 25, 2020 by 11:59 PM Pacific Daylight Time (PDT). Proposals should be submitted as a single PDF in an email to rhorowitz@naccho.org with subject line: "CT GC Patient Self-collection RFA."

For questions, contact:
Rebekah Horowitz, JD/MPH, Senior Analyst, HIV, STI, and Viral Hepatitis
rhorowitz@naccho.org