Project Determination

Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS)

Project ID:	0900f3eb82433c7d
Accession #:	NCHHSTP-BSEB-8/22/24-202f6
Project Contact:	Shacara Johnson
Organization:	OS/OS/OSI
Status:	Pending Regulatory Clearance
Intended Use:	Project Determination
Estimated Start Date:	01/01/25
Estimated Completion Date:	07/31/29
CDC/ATSDR HRPO/IRB Protocol#:	
OMB Control#:	
End of Human Research Date:	

Description

Priority
Standard
Date Needed
09/18/24
CDC Priority Area for this Project
Readiness and Response
Determination Start Date
09/06/24
Description
Gonorrhea is the second most commonly reported nationally notifiable disease in the United States with over 648,056 cases reported in 2022. Untreated GC can lead to pelvic inflammatory disease, ectopic pregnancy and infertility in women, epididymitis in men, disseminated infection in men and women, and can facilitate

HIV acquisition and transmission. Timely and effective treatment for GC can prevent these severe adverse health outcomes and onward transmission in the community. However, Neisseria gonorrhoeae has progressively acquired resistance to each of the antimicrobial agents that have been recommended for treatment over the past 70 years. Additionally, there is grave concern about N. gonorrhoeae becoming less susceptible to third generation cephalosporins, including ceftriaxone. Ceftriaxone is the current recommended therapy for uncomplicated urogenital gonorrhea. As the antibiotic pipeline has dwindled, the threat of untreatable GC continues to increase. Development and spread of strains with cephalosporin resistance will severely complicate control and prevention of GC. Because GC is primarily diagnosed through nucleic acid amplification testing (NAAT) technologies, rather than culture, few clinicians readily have access to gonococcal antimicrobial susceptibility testing (AST). CARGOS builds on the foundational work and infrastructure established under the three previous project initiatives at CDC– the Gonococcal Isolate Surveillance Program (GISP), the enhanced Gonococcal Isolate Surveillance Program (eGISP), and Strengthening the U.S. Response to Resistant Gonorrhea (SURRG). CARGOS is a comprehensive strategy designed to streamline and improve the coordination of Antimicrobial Resistance (AR) surveillance and preparedness and response activities focused on Neisseria gonorrhoeae (GC) and expand capacity to include other STIs with emerging AR in the United States. CARGOS will support rapid detection of resistant gonorrhea, get actionable information into the hands of healthcare providers (to support appropriate treatment of individual patients) and local health departments (to support rapid public health response to slow the spread of resistant infections in the community), and support multiple national public health strategies including the 2020–2025 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) and STI National Strategic Plan for the United States 2021–2025.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission

No

IMS Activation Name

Not selected

Submitted through IMS clearance matrix

Not selected

Primary Scientific Priority

Not selected

Secondary Scientific Priority (s)

Not selected

Task Force Responsible

Not selected

CIO Emergency Response Name

Not selected

Epi-Aid Name

Not selected

Lab-Aid Name

Not selected

Assessment of Chemical Exposure Name

Not selected

Goals/Purpose

The project purpose is to: (1) strengthen local epidemiologic capacity to detect, monitor, and respond to AR in STIs, (2) improve coordination of AR in STI preparedness and outbreak response activities, (3) enhance local laboratory testing for surveillance, reporting, and response, and (4) enhance coordination between epi-lab-health information technology for public health action.

Objective

The core objectives of CARGOS are to: (1) monitor trends in antimicrobial susceptibilities of gonorrhea and STIs in the U.S. and (2) strengthen state and local capacity to rapidly detect and respond to threats of antimicrobial resistance. The goals of this activity are to inform a more comprehensive understanding of trends and determinants of drug-resistant gonorrhea, monitor for the emergence of resistance, and provide a robust evidence base for directing public health action.

Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?

No

Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?

No

Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?

Yes

Activities or Tasks

New Collection of Information, Data, or Biospecimens

Target Population to be Included/Represented

General US Population

Tags/Keywords

Gonorrhea; Microbial; Drug Resistance; STIs; Surveillance; Preparedness & Response

CDC's Role

Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided; CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens; CDC employees will participate as co-authors in presentation(s) or publication(s); CDC employees will provide substantial technical assistance or oversight; CDC is providing funding

Method Categories

Analytic Services (can be data/specimen TA for non-research,research,investigations); Culture; Surveillance Support; Technical Assistance

Methods

Per clinic protocol (determined locally), eligible patients will have swab(s) collected for gonorrhea culture at anatomic sites of exposure. The local public health lab will perform cultures and conduct AST via E-test on all positive cultures (isolates). All purified bacterial isolates will be sent onto a regional laboratory for

confirmatory AST via agar dilution, and whole genome sequencing for molecular characterization will be conducted on a subset (no human DNA will be included in the sample). Public health disease intervention specialists (DIS) will conduct case investigations and partner services activities (using a standardized but locally modifiable STI case investigation protocol) for all patients. If a patient is identified as having a detected resistant gonorrhea isolate, then DIS will collected data from patient(s) about recent sexual exposures and elicit names and contact information for their recent sexual contacts who might benefit from STD screening as well as refer them for treatment. DIS will attempt to contact named sexual partners and refer them to the local STD clinic for STD testing (including gonorrhea culture) and treatment (as appropriate). DIS will attempt to contact them and refer them to the STD clinic for testing and treatment (as appropriate). Demographic, clinical, and laboratory data will be abstracted from the health records at participating clinics by the local epidemiological coordinator. Unique patient identifiers will be assigned locally that will not contain personally identifiable information. These de-identified data will be linked by the locally assigned identifier and transmitted to CDC following the Secure Access Management Service protocols.

Collection of Info, Data, or Bio specimens

Per clinic protocol (determined locally), eligible patients will have swab(s) collected for gonorrhea culture at anatomic sites of exposure. Demographic, clinical, and laboratory data will be abstracted from the health records at participating clinics by the local epidemiological coordinator. Unique patient identifiers will be assigned locally that will not contain personally identifiable information. These de-identified data will be linked by the locally assigned identifier and transmitted to CDC following the Secure Access Management Service protocols.

Expected Use of Findings/Results and their impact

Data collected in this project will be used to inform antimicrobial resistant gonorrhea prevention and control efforts in the US. Findings will be disseminated through peer reviewed journal articles and conference presentations.

Could Individuals potentially be identified based on Information Collected?

No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
CDC Cooperative Agreement	CK24-0002 Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases			5	6500000.00

HSC Review

HSC Attributes

Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research. This activity meets the definition of public health surveillance as defined in 46.102(l)(2). The purpose of this activity is to (1) strengthen local epidemiologic capacity to detect, monitor, and respond to AR in STIs, (2) improve coordination of AR in STI preparedness and

HSC Review

HSC Attributes
outbreak response activities, (3) enhance local laboratory testing for surveillance, reporting, and response, and (4) enhance coordination between epi-lab-health information technology for public health action. Major changes (amendments) should be submitted for re-review to ensure the changes do not affect this determination.
Yes

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO?
No

Will you be working with an outside Organization or Institution? No

Institutions

Institution	FWA #	FWA Exp. Date	Funding	Funding Restriction Amount

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been lifted

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution

Institution	Regulatory Coverage	IRB Review Status

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Citi Good Laboratory Practice Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
LashondraBerman	08/17/2026					Project Coordinator	zhj5@cdc.gov	404-639-1686	COMBATING ANTIMICROBIAL RESISTANT GONORRHEA AND OTHER STIs
ShacaraJohnson	05/22/2026					Program Lead	uzx1@cdc.gov	404-718-1149	BEHAVIORAL SCIENCE & EPIDEMIOLOGY BRANCH

DMP

Proposed Data Collection Start Date	06/01/25
Proposed Data Collection End Date	05/31/30
Proposed Public Access Level	Non-Public
Reason for not Releasing the Data	Country/Jurisdiction owns the data with protections under their laws and regulations
Public Access justification	Clinical, laboratory, and epidemiological data are data collected and stored by jurisdictions as part of surveillance and public health activities.
How Access Will Be Provided for Data	All data transmitted to CDC are de-identified and Secure Access Management Service protocols.
Plans for archival and long-term preservation of the data	

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States	New York	
United States	Nevada	Clark County
United States	Minnesota	Hennepin County
United States	Michigan	Oakland County
United States	Massachusetts	Suffolk County
United States	Indiana	Marion County
United States	Illinois	Cook County
United States	Hawaii	Honolulu County
United States	Colorado	Denver County
United States	California	San Francisco County
United States	California	San Diego County
United States	California	Orange County
United States	California	Los Angeles County
United States	Arizona	Maricopa County
United States	Alabama	Jefferson County
United States	Wisconsin	Milwaukee County
United States	Washington	King County
United States	Texas	Dallas County
United States	Pennsylvania	Philadelphia County
United States	North Carolina	Guilford County
United States	Missouri	Jackson County

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	08/30/24	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		09/06/24	Nhim_Kunthea (xmh8) CTR OMB/PRA Coordinator