U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/27/23

Title:	Strengthening the U.S. Response to Resistant Gonorrhea (SURRG)
Project Id:	0900f3eb82088829
Accession #:	NCHHSTP-BSEB-1/12/23-88829
Project Contact:	Emily R Learner
Organization:	NCHHSTP/DSTDP/BSEB
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	01/02/2023
Estimated Completion Date:	07/31/2026
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1242

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	3/24/23	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		3/27/23	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

ICRO: **PRA Applies**	OMB Approval date: 4/5/22 OMB Expiration date: 4/30/25	3/27/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Determination Start Date:	03/15/23
Description:	GC is the third most commonly reported communicable disease in the United States with over 677,000 cases reported in 2020. 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). While CDC#s Gonococcal Isolate Surveillance Project (GISP) is critically important for monitoring long-term trends in gonococcal susceptibility to inform treatment guidelines, the susceptibility results are not available quickly enough to allow for rapid local responses to resistant strains. Developing local and state public health capacity for timely detection of and rapid response to emerging resistant GC threats is urgently needed to mitigate the spread of resistant GC. Activities funded as a part of this project will strengthen state and local GC public health infrastructure and build capacity in high-risk local jurisdictions to support rapid detection of and response to threats of antibiotic-resistant GC. High-risk jurisdictions include: (1) geographic areas at elevated risk of experiencing emergence of resistant GC based on the historical development of antibiotic resistance in the U.S (e.g., areas in the western part of the U.S.); (2) areas with local GC epidemics that include large percentages of gay, bisexual, or other men who have sex with men (MSM); or (3) geographic areas with high GC rates.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	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	- Enhance timeliness and sensitivity of local surveillance for resistant gonorrhea - Strengthen local resistant gonorrhea response capacity (programmatic, laboratory and epidemiological) - Enhance local capacity to rapidly conduct gonorrhea case investigations and partner services, to ensure appropriate treatment of patients with resistant gonorrhea infections, and halt the spread of identified resistant strains - Evaluate yield and impact of gonorrhea case investigations for halting spread of identified resistant strains - Develop deeper understanding of sexual networks and gonorrhea transmission (using observational clinical, epidemiological, network, and genomic data) to identify opportunities for innovative approaches to gonorrhea prevention and control
Objective:	- Substantially increase local specimen collection for Neisseria gonorrhoeae culture and antibiotic susceptibility testing (AST) - Build and expand local capacity to routinely conduct rapid antibiotic susceptibility testing (AST) capacity (via Etest with ~5 day turnaround) - Strengthen local data system functionality and interoperability to strengthen surveillance and programmatic response capacity - Build capacity for local STD programs to conduct enhanced cluster field investigations of and partner services for persons diagnosed with gonorrhea of public health significance (such as resistant/reduced susceptibility) and those in his/her sexual network - Ensure appropriate treatment of patients diagnosed with gonorrhea with resistance/reduced susceptibility; ensure partners are tested and treated - Utilize genomic data of N. gonorrhoeae isolates to support and inform local cluster investigations - Conduct local and multi-site analyses using clinical, epidemiological, network, and genomic data to identify opportunities for inform cluster field investigations and develop and evaluate prevention/control interventions
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	No
Project does not incorporate elements of health equity science:	Yes
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Gonorrhea ; Drug Resistance, Microbial
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 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
	- Per clinic protocol (determined locally), eligible patients will have swab(s) collected for gonorrhea culture and NAAT at all anatomic

Methods:	sites of exposure - The local public health lab will perform cultures and conduct AST via Etest 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 cluster case investigations and partner services activities (using a standardized but locally modifiable SURRG case investigation protocol) for all patients identified as having resistant gonorrhea. As local capacity builds, investigations and partner services for non-resistant infections can be conducted. DIS will collected data from patients about recent sexual exposures and elicit names and contact information for their recent sexual contacts and up to 2 social contacts who might benefit from STD screening. DIS will attempt to contact named sexual partners and social contacts, 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 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 Biospecimen:	- Per clinic protocol (determined locally), eligible patients will have swab(s) collected for gonorrhea culture and NAAT at all anatomic sites of exposure - Demographic, clinical, and laboratory data will be abstracted from the health records 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 Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	CK19-1904 Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases				

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects	
Do you anticipate this project will be exempt research or non-exempt research	

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection

Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Emily Learner	11/29/2024		12/06/2021		Program Lead	kvd7@cdc.gov	404-718-7339	BEHAVIORAL SCIENCE & EPIDEMIOLOGY BRANCH
Kerry Mauk	08/17/2023	09/24/2021			Data Use Contact	odf4@cdc.gov	404-718-6272	EPIEMIOLOGY RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 8/1/22

Proposed Data Collection End Date: 7/31/23

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing 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:

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date

Dataset yet to be added...

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	03/27/2023	NOA 0920-1242 (2022).	Notice of Action	NOA 0920-1242_2022.pdf
Current	Learner_Emily (kvd7) Project Contact	03/15/2023	Attaching original project determination which includes HS review (non-research determination)	Other-Enter new type	SURRG Non-Research Determination-and-Approval-Form_FNL_6-20-17.pdf
Current	Learner_Emily (kvd7) Project Contact	03/15/2023	OMB NOA	Other-Enter new type	SURRG OMB NOA thru 4-30-2025.pdf