Project Determination

Gonococcal Isolate Surveillance Project (GISP) - Core and Enhanced Components

Project ID:	0900f3eb81c9f334
Accession #:	NCHHSTP-ST-2/5/21-93d04
Project Contact:	Sancta St Cyr
Organization:	OS/OS/OSI
Status:	Pending Regulatory Clearance
Intended Use:	Project Determination
Estimated Start Date:	01/01/87
Estimated Completion Date:	12/31/27
CDC/ATSDR HRPO/IRB Protocol#:	
OMB Control#:	

Description

Priority

Standard

Date Needed

02/26/21

Determination Start Date

02/12/21

Description

The Gonococcal Isolate Surveillance Project (GISP) was created in 1986 to monitor trends in antimicrobial susceptibilities of N. gonorrhoeae in the United States. Data collected from GISP have been used to inform treatment recommendations for gonorrhea since 1989. To increase capacity to detect and monitor resistant gonorrhea and improve the specificity of GISP, an enhanced component to GISP (eGISP) was added to the sentinel surveillance system in 2017. The resubmission of this project determination is to combine the eGISP component with the core component of GISP into one project determination, to include the collection of remnant nucleic acid amplification tests as well as culture specimens for this surveillance activity, and to include collection of new antimicrobial treatment dosages as a

result of the 2020 update to the gonorrhea treatment recommendations.

IMS/CIO/Epi-Aid/Chemical Exposure Submission

No

IMS Activation Name

Not selected

Select the primary priority of the project:

Not selected

Select the secondary priority(s) of the project:

Not selected

Select the task force associated with the response:

Not selected

CIO Emergency Response Name

Not selected

Epi-Aid Name

Not selected

Assessment of Chemical Exposure Name

Not selected

Goals/Purpose

1) To provide a scientific basis for the selection of therapies for gonorrhea to be recommended by CDC in the STD Treatment Guidelines; 2) To enhance surveillance of antimicrobial resistant N. gonorrhoeae in the United States and increase national capacity to detect and monitor resistant gonorrhea, including among important populations, such as gay, bisexual, and other men who have sex with men (MSM, a population that experiences higher prevalence of resistance), and women (a population from whom specimens are not routinely systemically collected for surveillance of resistance) in the United States.

Objective

1) To monitor N. gonorrhoeae antimicrobial susceptibilities trends; 2) To characterize patients with gonorrhea attending STD clinics, particularly those infected with N. gonorrhoeae that are not susceptible to recommended antimicrobials; 3) To phenotypically and genotypically characterize isolates to describe the diversity of N. gonorrhoeae antimicrobial resistance; 4) To strengthen US phenotypic and genotypic surveillance of gonococcal antimicrobial resistance to improve national prevalence estimates across different populations; 5) To improve clinical and laboratory capacity to conduct N. gonorrhoeae culture and antimicrobial susceptibility testing in the United States; 6) To expand the number of gonococcal isolates and genetic sequences available for inclusion in the CDC isolate archive repository; 7) To improve the specificity of gonococcal antibiotic resistance surveillance by distinguishing N. gonorrhoeae from N. meningitidis in specimens from the urethra and other anatomic sites and to improve the prevalence estimates of N. meningitidis at the urethra and other anatomic sites; 8) To improve the understanding of the epidemiology and resistance patterns of meningococcal isolates collected from patients attending STD clinics, particularly those infected with N. meningitidis that present clinically and microbiologically similar to those infected with N. gonorrhea

Activities or Tasks

New Collection of Information, Data, or Biospecimens

Target Population to be Included/Represented

General US Population

Tags/Keywords

Neisseria gonorrhoeae: Neisseria meningitidis: Neisseria: Gonorrhea: Sexually Transmitted Diseases, Bacterial: Drug Resistance, Bacterial: Drug Resistance: Drug Resistance, Multiple, Bacterial: Public Health Surveillance: Sentinel Surveillance: Nucleic Acid Amplification Techniques: Female Urogenital Diseases: Genital Diseases, Female: Genital Diseases, Male: Male Urogenital Diseases

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 is providing funding

Method Categories

Analytic Services (can be data/specimen TA for non-research,research,investigations)

Methods

The Gonococcal Isolate Surveillance Project (GISP) is made up of a core GISP component and an enhanced GISP component (eGISP). There are on average 30 sites in the US that participate annually in GISP with an average of 5 sites changing annually. Participating jurisdictions come from all regions of the US (West, Midwest, South and Northeast). All sentinel sites are responsible for the monthly collection and submission of (1) gonococcal isolates to assigned GISP regional laboratories (CDC-supported Antibiotic Resistance Laboratory Network, ARLN), and (2) clinical/demographic data associated with GISP isolates to CDC. Urethral Neisseria gonorrhoeae isolates (based on a presumptive or confirmed identification) are collected from the first 25 men with symptomatic urethral gonococcal infection each month as part of core GISP surveillance. The overall goal is for each sentinel site to provide at least 300 isolates per year. To better describe the specificity of gonococcal surveillance and the gonococcal resistance patterns by gender and anatomic site, a subset of participating sentinel sites can A) collect additional isolates from (1) the first 25 men or women with rectal or pharyngeal gonorrhea, (2) the first 25 women who undergo speculum examination who are diagnosed with cervical gonorrhea, and (3) all patients found to have a presentation similar to gonorrhea but isolates identified as Neisseria meningitidis; and/or B) submit remnant specimens from local nucleic acid amplification testing (NAAT) to CDC for molecular evaluation. The gonococcal isolates are sent to the assigned GISP regional laboratory (CDC-supported ARLN) for antimicrobial susceptibility testing and selection for whole genome sequencing. The meningococcal isolates are sent directly to CDC for evaluation. Select sentinel sites participating in molecular surveillance ship gonococcal positive remnant samples from local NAAT testing directly to CDC for molecular evaluation of known resistance-conferring genetic mutations. All sentinel sites collect and transmit clinical and demographic data as part of core GISP surveillance activities and additional data on anatomic site of infection, results of gonococcal NAAT, and site-assigned unique patient identifiers for both enhanced GISP surveillance activities. Gonococcal isolates are subcultured from the selective primary medium to a non-inhibitory medium to obtain a pure culture of the isolate. If NAAT for gonorrhea is performed for a specific specimen and is found to be negative, the isolate should not be shipped to the regional laboratory as part of core GISP activities. If the isolate is presumptively identified as a meningococcal isolate and the submitting site participates in enhanced GISP activities, the isolate should be shipped directly to CDC. Regional ARLN laboratories are responsible for determining β-lactamase production and antimicrobial susceptibilities of gonococcal isolates received from the sentinel sites and shipping selected isolates to CDC. Any meningococcal isolates identified by the regional ARLN should be shipped to CDC. Antimicrobial susceptibilities (reported as minimum inhibitory concentrations, MICs) to 7-10 antimicrobials are determined by the agar-dilution procedure.

Collection of Info, Data, or Bio specimens

Urethral specimens (based on a presumptive or confirmed N. gonorrhoeae identification) are collected from the first 25 men with symptomatic urethral gonococcal infection each month. Rectal and pharyngeal isolates are collected from consecutive men and women presenting in the clinic who report rectal and/or pharyngeal exposure who are having a NAAT performed until 25 rectal and/or pharyngeal isolates identified as N. gonorrhoeae have been collected. Endocervical isolates are collected from consecutive women who present to the clinic who undergo pelvic examinations and are likely to be infected with N. gonorrhoeae, including those with mucopurulent cervicitis, known contacts to gonorrhea, and those with a positive NAAT at any site of interest returning for treatment until 25 endocervical isolates identified as N. gonorrhoeae have been collected. Urethral, endocervical or rectal specimens suspected of being possible N. meningitidis isolates are collected from men and women each month. In order to improve the recovery of viable culture, it is recommended that two swabs be used to collect the sample at the aforementioned anatomical sites. One swab is for culture recovery by rolling the swab across the center of the modified Thayer-Martin plate. Then, with the same sampling swab, perform a continuous (zigzag) streak down and away from the inoculated-center line. The first swab can then be used for Gram stain procedure. The second swab may be used for NAAT analysis. In cases where two swabs cannot be obtained, it is recommended that the lone specimen-swab be processed in the following order. First, the specimen swab is used for plate inoculation by rolling the swab across the modified Thayer-Martin plate. With a sterile inoculating loop, perform a continuous (zigzag) streak down and away from the inoculated-center line. After inoculating the plate for culture, the specimen swab can be used for making a Gram stain smear. Make a smear on a glass slide using the tip-area of the specimen swab. Use this smear for Gram stain analysis. Finally, drop the specimen swab into NAAT collection/buffer tube for NAAT analysis. Remnant NAATs from participating sites found to be positive for gonorrhea are later shipped directly to CDC for molecular evaluation (e.g., genetic extraction, purification and testing for known resistance-conferring mutations). Clinical and demographic data should be submitted for each patient from whom a GISP isolate, eGISP isolate, or remnant NAAT is submitted. Data may be obtained through review of medical records by clinic staff. Line-listed de-identified clinical and demographic data elements associated with each isolate are collected by the sentinel site. eGISP sentinel sites assign a unique identifier to the patient (“Patient ID”), so as to enable identification of multiple isolates that are collected from the same patient and include this identifier with the line-listed transmitted data. Clinical and demographic data should be sent to CDC monthly as an Excel spreadsheet. Sites are provided with the Excel template and data dictionary. Data should be received at CDC no more than four weeks after the end of the month in which the corresponding isolates or remnant NAATs were provided.

Expected Use of Findings/Results and their impact

All antimicrobial susceptibility data are returned each month to sentinel sites. Sentinel sites are encouraged to routinely review the data and use them for determining local needs. Nationally, all GISP data are analyzed for susceptibility trends and are often stratified by clinical site, region, gender and gender of sex partners. GISP data are routinely published and disseminated in annual STD surveillance reports, peer-reviewed publications, and MMWRs, and are routinely presented at scientific conferences. GISP data have also contributed to the national gonorrhea treatment recommendations since 1989. GISP findings are routinely shared with local collaborators and GISP participating clinics are acknowledged when data are published.

Could Individuals potentially be identified based on Information Collected?

No

Will PII be captured (including coded data)?

No

Does CDC have access to the Identifiers (including coded data)?

No

Is an assurance of confidentiality in place or planned?

No
Is a certificate of confidentiality in place or planned?
No
Is there a formal written agreement prohibiting the release of identifiers?
No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award
CDC Cooperative Agreement	Epidemiology and Laboratory Capacity (ELC) Program (CDC-RFA-CK19-1904)	CDC-RFA-CK19-1904		

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office:
No

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #
Florida Department of Health					CDC-RFA-CK19-1904
Indiana State Department of Health					CDC-RFA-CK19-1904
North Carolina Department of Health and Human Services					CDC-RFA-CK19-1904
Alabama Department of Public Health	FWA00003283	12/16/24	Alabama Dept Public Hlth-Panel A IRB #1	06/04/23	CDC-RFA-CK19-1904
Alaska Division of Public Health	FWA00018306	11/12/24	U Alaska Anchorage IRB	01/14/24	CDC-RFA-CK19-1904

			#1		
Arizona Department of Health Services, Human Subjects Review Board	FWA00002311	01/03/25	Arizona Department of Health Services, Human Subjects Review Board IRB #1	01/08/23	CDC-RFA-CK19-1904
California Health & Human Services Agency	FWA00000681	04/16/24			CDC-RFA-CK19-1904
Chicago Department of Public Health	FWA00001184	03/01/24	Chicago Dept Public Hlth IRB #1	11/15/21	CDC-RFA-CK19-1904
Colorado Department of Public Health & Environment	FWA00003044	03/02/25			CDC-RFA-CK19-1904
District of Columbia Dept of Hlth	FWA00003034	09/26/22			CDC-RFA-CK19-1904
Hawaii State Dept Hlth	FWA00000118	03/29/22			CDC-RFA-CK19-1904
Los Angeles County Dept of Hlth Services & Los Angeles County Dept of Public Hlth	FWA00000071	05/17/21	Los Angeles Co Dept Hlth Services IRB #1 - Public Hlth	07/29/23	CDC-RFA-CK19-1904
Louisiana Department of Health	FWA00026681	03/19/23	Louisiana Department of Health IRB #2	03/16/21	CDC-RFA-CK19-1904
Maryland Department of Health	FWA00002813	03/07/23	Maryland Dept of Hlth & Mental Hygiene IRB #1	03/16/21	CDC-RFA-CK19-1904
Michigan Department of Health and Human Services	FWA00007331	09/12/24			CDC-RFA-CK19-1904
Minnesota Department of Health	FWA00000072	03/24/22			CDC-RFA-CK19-1904
Mississippi State Department of Health	FWA00021429	05/14/24	Mississippi State Department of Health IRB #1	09/22/23	CDC-RFA-CK19-1904

Missouri Dept of Hlth & Senior Services	FWA00001948	07/28/25	Missouri Dept of Hlth & Senior Services IRB #1	10/01/23	CDC-RFA-CK19-1904
New Jersey Department of Health	FWA00029683	06/24/25	Rowan University School of Osteopathic Medicine IRB #1	12/15/23	CDC-RFA-CK19-1904
New Mexico Department of Health	FWA00030150	09/29/25	New Mexico State U IRB #1	07/03/22	CDC-RFA-CK19-1904
New York City Dept of Hlth & Mental Hygiene	FWA00009459	08/06/25	New York City Dept of Hlth & Mental Hygiene IRB #1	08/06/23	CDC-RFA-CK19-1904
New York State Dept of Hlth	FWA00003700	10/01/25			CDC-RFA-CK19-1904
Ohio Dept of Hlth	FWA00001963	01/29/25	Ohio Dept of Hlth IRB #1	01/15/24	CDC-RFA-CK19-1904
Oregon Health Authority - Public Hlth Division	FWA00000520	10/23/24	DHS-Health Svces/Multnomah Co Public Hlth IRB #1	12/11/22	CDC-RFA-CK19-1904
Philadelphia Department of Public Health	FWA00003616	10/28/25	Philadelphia Dept of Public Hlth IRB #1	11/06/21	CDC-RFA-CK19-1904
San Francisco Dept of Public Hlth	FWA00000162	03/05/23			CDC-RFA-CK19-1904
Southern Nevada Health District	FWA00023704	10/23/24	U of Nevada, Las Vegas IRB #1 -- Biomedical Sciences	01/03/23	CDC-RFA-CK19-1904
Texas Health and Human Services Commission - Central Administration IRB2	FWA00028877	12/18/24	Texas Health and Human Services Commission - Central Administration	03/20/23	CDC-RFA-CK19-1904

			IRB2 IRB		
Washington State Department of Health	FWA00000327	03/26/21			CDC-RFA-CK19-1904
Wisconsin Dept of Health Services	FWA00002517	01/20/24			CDC-RFA-CK19-1904

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Brian Raphael	02/01/2024	01/08/2022		01/28/2022	Co-Investigator	elx9@cdc.gov	404-639-4292	LABORATORY REFERENCE AND RESEARCH BRANCH
Cau Pham	10/03/2022	01/07/2022		04/22/2022	Co-Investigator	whi4@cdc.gov	404-718-5642	GONORRHEA, CHLAMYDIA AND MYCOPLASMA GENITALIUM TEAM
Ellen Kersh	01/27/2023	12/20/2021			Co-Investigator	egk6@cdc.gov	404-639-2728	LABORATORY REFERENCE AND RESEARCH BRANCH
Hillard Weinstock	02/14/2023	12/18/2021	12/20/2021		Co-Investigator	hsw2@cdc.gov	404-639-2059	SURVEILLANCE AND DATA MANAGEMENT BRANCH
Kristen Kreisel	01/02/2022	09/07/2021		09/21/2021	Co-Investigator	ltq1@cdc.gov	404-718-5148	SURVEILLANCE TEAM
Sancta St Cyr	03/05/2022				Co-Investigator	oew3@cdc.gov	404-718-5447	SURVEILLANCE TEAM

DMP

Proposed Data Collection Start Date	01/01/21
Proposed Data Collection End Date	12/31/27
Proposed Public Access Level	Public
Public Access justification	The data will be shared with the public in aggregate form in published annual reports and scientific manuscripts. Additionally, the public can request from CDC, in writing, aggregate data for academic or public health use. PII is not collected by CDC and will not be available for request.
How Access Will Be Provided for Data	Line-listed data will not be made available to the general public without a written request and review by CDC staff. All line-listed data (which does not contain PII) is housed on CDC servers with restricted access that is limited to project staff.
Plans for archival and long-term preservation of the data	Isolates and data collected through GISP are securely archived at CDC. Archived isolates and data may be used, after internal evaluation by project staff, for additional surveillance analyses after the year data were collected.

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States		

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	02/11/21	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		02/12/21	Bonds_Constance (akj8) CTR OMB/PRA Coordinator
ICRO: **Returned with No Decision**		02/12/21	Zirger_Jeffrey (wtj5) ICRO Reviewer