Project Determination

Mycoplasma Genitalium Treatment Failure Registry

Project ID:	0900f3eb81ae8d81
Accession #:	NCHHSTP-CT-2/27/20-e8d81
Project Contact:	Park_Ina (vkq1)
Organization:	OS/OS/OSI
Status:	Pending Regulatory Clearance
Intended Use:	Project Determination
Estimated Start Date:	04/01/20
Estimated Completion Date:	03/31/23
CDC/ATSDR HRPO/IRB Protocol#:	N/A
OMB Control#:	pending--submitting for eclearance before OMB

Description

Priority

Standard

Date Needed

03/20/20

Determination Start Date

03/09/20

Description

Registry of patients experiencing treatment failure after CDC recommended antibiotic therapy for M. genitalium urogenital or anogenital infection.

Goals/Purpose

The purpose of the registry is to conduct surveillance on which second-line antibiotics are in use for Mycoplasma genitalium treatment failure and monitor genetic markers of antibiotic resistance among treatment failure cases throughout the United States. Currently there are no guidelines for patients who fail CDC-recommended antibiotic therapy, and available treatment options are extremely limited.

Objective

Specific objectives of the registry include describing: 1) Number of treatment failure cases reported annually; 2) Which second-line antibiotic therapies currently in use in patients experiencing treatment failure; 3) Demographic and behavioral factors among patients with treatment failure; 4) Proportion of specimens from treatment failure patients with molecular markers of macrolide, tetracycline, and fluoroquinolone resistance; 5) Final disposition of patients with treatment failure as relates to clinical response and organism eradication.

Activities or Tasks

New Collection of Information, Data, or Biospecimens

Target Population to be Included/Represented

General US Population: Children: Patient

Tags/Keywords

Sexually Transmitted Diseases, Bacterial: Public Health Surveillance: Treatment Failure

CDC's Role

CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens

Method Categories

Convenience Sample

Methods

The respondent universe consists of clinicians who care for patients with Mycoplasma genitalium. Clinicians may come from private health care practices, publicly-funded health care facilities, hospitals, universities, medical centers, federal agency clinics (e.g. Indian Health Service), and state and local health departments. Clinicians who respond will represent a convenience sample of US health care providers. The population eligible for surveillance through the M. genitalium Treatment Failure Registry ("the Registry") include persons of any gender who are infected with anogenital M. genitalium. The following patients are eligible to be included in the Registry: 1) Patients with urogenital or anorectal symptoms and laboratory confirmation of M. genitalium using a nucleic acid amplification test (NAAT) AND 2) Received at least seven days of moxifloxacin for antibiotic therapy AND 3) Remain persistently symptomatic (subjective) and have either a. Elevations in urine WBC or persistent discharge AND/OR b. Have a persistently positive NAAT test for M. genitalium. At this point, we do not know how many patients in the US will experience treatment failure annually, as case reports up until this point have been uncommon, but have estimated up to 100 cases reported per year. Identification of Cases: CDC DSTDP will inform its grantees (e.g., National Network of STD Clinical Prevention Training Centers-NNPTC, state and territorial health departments), academic, clinical, and laboratory partners about the Mycoplasma genitalium Treatment Failure Registry ("the Registry") through various communication channels (e.g., direct email, Dear Colleague letters). Cases may come to the attention of CDC through contacts with academic research centers and clinical inquiry systems such as CDC-INFO or the STD Clinical Consultation Network (STDCCN). CDC will establish a designated Registry email address where providers can communicate directly with the Registry staff.

Collection of Info, Data, or Bio specimens

Respondent clinicians will complete the Case Report Form for the Mycoplasma genitalium Treatment Failure Registry (Att 1) which will be made available on the CDC DSTDP website and by request from the Registry Project Officer. The Case Report Form will collect categories of information in identifiable format from respondent clinicians such as: clinician's name, work mailing address, work phone numbers, work email address. The responding provider will generate a unique identifier for the case report form. This will allow linking of patient data with laboratory testing data, if specimens are sent to CDC for testing. This will also allow

linkage of data internally in case a patient experiences multiple episodes of treatment failure. The unique identifier will consist of the patients first and last initial, 2-digit year of birth, and last 4 digits of the Medical Record Number. (e.g., John Smith, born 1973, MRN 1234567 = JS73-4567). There will be no links to personally identifiable information. Reporting providers will be asked to submit the two-page case report form (either by secure fax or email) to CDC DSTDP. Upon receipt, Case Report Form data will be entered into an electronic database at CDC. Future analysis of provider-level data will be limited to the reporting providers' state, to determine if there is regional clustering of treatment failure cases. Patient level characteristics will be analyzed in aggregate. No identifying information will be sent to the CDC, other than the dates of antibiotic treatment. If specimens are available, remnant specimens from patients with M. genitalium treatment failure will be sent to the DSTDP laboratory to be tested for genetic mutations associated with antibiotic resistance to macrolides, fluroquinolones, and tetracyclines. Specimen test results will be analyzed in aggregate to determine the prevalence of antibiotic resistance markers. The submitting laboratory will be asked to remove labels with PHI and replace them with a label containing the CDC unique identifier. (The unique ID will be provided to the submitting laboratory by the Registry Project Officer). The Registry Project Officer will liaise between the submitting laboratory and the CDC Laboratory to coordinate the submission of specimens.

Expected Use of Findings/Results and their impact

The resulting data will be used to inform national treatment recommendations from the CDC for Mycoplasma genitalium.

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

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office:

No

Regulation and Policy

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #

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
Laura Bachmann	05/13/2021	06/03/2021		12/09/2021	Principal Investigator	frg6@cdc.gov	404-718-5053	PROGRAM DEVELOPMENT AND QUALITY IMPROVEMENT BRANCH

DMP

Proposed Data Collection Start Date	04/01/20
Proposed Data Collection End Date	03/31/23
Proposed Public Access Level	Public
Public Access justification	Frequencies will be made available to the public. The data will also be presented in aggregate at scientific conferences and in publications to inform future treatment of patients experiencing treatment failure from Mycoplasma genitalium.
How Access Will Be Provided for Data	There are several safeguards in place to handle data submitted to the CDC. Data will be stored and managed based on current CDC/OCISO (Office of the Chief Information Security Officer) requirements and standards. This includes protecting stored data within the CDC Internet Firewall. The data are stored and managed based on current CDC/OCISO requirements and standards which also includes the process for handling security incidents and the event monitoring and incident response. All administrative controls required by OCISO are validated through a “Certification and Authorization” (C&A) process as conducted by OCISO prior to moving any software application into “Production” on the CDC network. Files are backed up daily and stored both onsite in accordance

	with CDC standards and OCISO guidelines. All users' access is "role based" and reflects a "need to know" policy established by CDC. Accountability is maintained with a user access log file which tracks users' access to the system. The CDC will not include any information in reports that may identify cases or patients, including specified dates of diagnosis and treatment. Only deidentified data will be presented in case reports or in aggregate. Aggregate data will not be stratified into subcategories that might allow for identification of individuals.
Plans for archival and long-term preservation of the data	Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule as mandated by OCISO. (http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy449.htm) Need for retention of records will be reviewed every 5 years with the Senior Records Liaison, in accordance with CDC Records Management Policy.

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	03/20/20	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		03/24/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator
ICRO: **Returned with No Decision**		03/24/20	Zirger_Jeffrey (wtj5) ICRO Reviewer