**Mycoplasma Treatment Failure Registry**

**Request for OMB Approval of a New Information Collection**
**OMB #0920-20OT**

**SUPPORTING STATEMENT B**

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Contact

**Name**: Laura Bachmann, MD, MPH
**Title**: Chief Medical Officer
**CIO**: Centers for Disease Control and Prevention,
National Center for HIV, Viral Hepatitis, STD, and TB (NCHHSTP)
**Division**: Division of STD Prevention, PDQIB
**Phone**: 404-718-5053
**Fax**: 404-639-8622
**Email**: frg6@cdc.gov

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**Section 1B. Collections of Information Employing Statistical Methods.**
This collection of information is used for program management and evaluation.

**1. Respondent Universe and Sampling 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 *Mycoplasma genitalium* Treatment Failure Registry ("the Registry") include persons of any gender who are infected with anogenital *Mycoplasma genitalium.* The following patients are eligible to be included in the Registry:

1) Patients with recurrent urethritis, cervicitis, or proctitis (see **Attachment 4)** and laboratory confirmation of *Mycoplasma genitalium* using a nucleic acid amplification test (NAAT) AND
2) Received CDC-recommended treatment for M. genitalium (at least seven days of moxifloxacin antibiotic therapy) AND
3) Remain persistently symptomatic (subjective) and have either
    a. Elevations in urine WBC or persistent discharge AND/OR
    b. Have a persist 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 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). 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.

**2. Procedures for the Collection of Information**.

Respondent clinicians will complete the Case Report Form for the *Mycoplasma genitalium* Treatment Failure Registry (**Attachment 4)** 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 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.

**3. Methods to Maximize Response Rates and Deal with Nonresponse**

Reporting to the registry is voluntary and only warranted for cases of treatment failure. Therefore, traditional methods for dealing with non-responders in research do not apply. Clinicians staffing the CDC INFO for DSTDP and the STD Clinical Consultation Network for NNPTC will be instructed to direct clinicians reporting M. genitalium treatment failure to Registry staff, so that reporting of cases may be facilitated. Information letters will be provided for clinicians to assist them in understanding the purpose and value of the Registry.

**4. Tests of Procedures or Methods to be Undertaken**

No part of this project entails an experimental design; rather, the design is descriptive in nature.

The *M. genitalium* Treatment Failure Registry Case Report Form was developed in consultation with the CDC and national experts on *M. genitalium.* The form was reviewed for clarity by five reviewers. Reviewer feedback was used to modify questions as needed.

Quantitative data from the case report forms will be analyzed using the Statistical Packages for the Social Sciences (SPSS) software program to calculate descriptive statistics of patient-level sociodemographic variables. This includes frequencies and cross-tabulations, as well as univariate distributions and correlations. The frequency analysis will give various chi-squared tests for association for categorical ordinal or nominal data. The reporting provider's state will be analyzed to determine whether treatment failure cases appear to cluster regionally within the US.

Results will be presented in graphic, written and verbal forms with annual written reports distributed throughout DSTDP, manuscripts and presentations at scientific conferences. Results may be shared with health departments and other government agencies, and/or healthcare organizations.

**5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Agency personnel responsible for receiving data:

Alexandra Coor, MPH
Centers for Disease Control and Prevention, DSTDP/PDQIB/OID
Phone: 404-639-6423, Fax: 404-639-8622, Email: yfu3@cdc.gov

Laura Bachmann, MD, MPH
Centers for Disease Control and Prevention, DSTDP/PDQIB/OID
**Phone**: 404-718-5053, **Fax**: 404-639-8622, **Email**: frg6@cdc.gov