



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-200T]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Mycoplasma genitalium Treatment Failure Registry" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 5, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Mycoplasma genitalium Treatment Failure Registry - New -
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB

Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of STD Prevention requests a three-year approval of an information collection request for the Mycoplasma genitalium Treatment Failure Registry, which will entail use of a standardized Case Report Form.

The primary goal of this activity is to establish a registry to monitor cases of Mycoplasma genitalium (*M. genitalium*) treatment failure in the United States. The project objectives are as follows: 1) Using existing clinical data, describe demographic and behavioral factors among patients with documented Mycoplasma genitalium who fail current CDC-recommended treatment, 2) Using existing clinical data, describe antibiotic regimens utilized among patients with *Mycoplasma genitalium* treatment failure, including documentation of clinical and microbiologic cure, 3) Using existing laboratory specimens, monitor genetic mutations associated with macrolide or fluroquinolone antibiotic resistance.

Data captured on the standardized Case Report Form will be analyzed to determine outcomes from usage of second-line antibiotic therapy for *M.gentialium*. These data may inform future CDC STD Treatment Guidelines. There are an estimated 100 respondents (anticipated to report once per year) who will be

clinicians in private and public health care settings. The data collection is necessary as there are no current national recommendations for patients who fail current CDC-recommended therapy for *M. genitalium*. Each case report form is anticipated to take up to 60 minutes to complete. This data collection provides CDC with information to determine which second-line treatments are most clinically effective, as well as determining antibiotic resistance patterns of *M. genitalium* throughout the US. There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection are 100 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)
Physician or Nurse Practitioner	M.genitalium Treatment Failure Registry Case Report Form	100	1	1

Jeffrey M. Zirger,
*Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.*