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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-0307]

[Docket No. CDC-2015-0072]

Proposed Data Collections Submitted for Public Comment and Recommendations

AGENCY: The Centers for Disease Control and Prevention (CDC)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed extension of the information collection entitled *The Gonococcal Isolate Surveillance Project (GISP)*, which is the only source in the United States of national, regional, and site-specific

gonococcal antibiotic resistance information that provides information to support informed and scientifically-based treatment recommendations.

To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0072 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

The Gonococcal Isolate Surveillance Project (GISP), (OMB No.0920-0307 exp. 08/31/2016) – Extension – National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The objectives of GISP are: (1) to monitor trends in antibiotic resistance of *Neisseria gonorrhoeae* strains in the United States and (2) to characterize resistant specimens. Surveillance of *N. gonorrhoeae* antibiotic resistance is important because: (1) nearly all gonococcal infections are treated empirically (meaning that healthcare providers have to decide how to treat their patients without having resistance testing results for individual patients upon which to base clinical decision-making) and susceptibility/resistance testing data are not routinely available in clinical practice; (2) *N. gonorrhoeae* has consistently demonstrated the ability to develop resistance to the antibiotics used for treatment; (3) effective treatment of gonorrhea is a critical component of gonorrhea control and prevention, and (4) untreated or inadequately treated gonorrhea can cause serious reproductive health complications.

GISP is the only source in the United States of national, regional, and site-specific gonococcal antibiotic resistance information. GISP provides information to support informed and scientifically-based treatment recommendations.

GISP was established in 1986 as a voluntary surveillance project and now involves 5 regional laboratories and 30 publicly funded sexually transmitted disease (STD) clinics around the country. The STD clinics submit up to 25 gonococcal specimens (or isolates) per month to the regional laboratories, which measure the ability of the specimens to resist the effects of multiple antibiotics. Limited demographic and clinical information corresponding to the isolates (and that do not allow identification of the patient) are submitted directly by the clinics to CDC.

During 1986-2015, GISP has demonstrated the ability to effectively achieve its objectives. The emergence of resistance in the United States to penicillin, tetracyclines, and fluoroquinolones among *N. gonorrhoeae* isolates was identified through GISP. Increased prevalence of fluoroquinolone-resistant *N. gonorrhoeae* (QRNG), as documented by GISP data, prompted CDC to update treatment recommendations for gonorrhea in CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006 and to release an MMWR article stating that CDC no longer recommended fluoroquinolones for treatment of gonococcal infections.

Information from GISP thus allowed public health officials to change treatment recommendations before resistance became widespread, ensuring that patients were able to be successfully treated. Recently, GISP isolates demonstrated increasing minimum inhibitory concentrations of cefixime, which can be an early warning of impending resistance. This worrisome trend prompted CDC to again update treatment recommendations and no longer recommend the use of cefixime as first-line treatment for gonococcal infections.

Under the GISP protocol, each of the 30 clinics submit an average of 20 isolates per clinic per month (i.e. 240 times per year) recorded on Form 1: Demographic/Clinical Data. The estimated time for clinical personnel to abstract data for Form 1: Demographic/Clinical Data is 11 minutes per response.

Each of the five Regional laboratories receives and processes an approximately 20 isolates from each referring clinic per month (i.e. 121 isolates per regional laboratory per month [based on 2011 specimen volume]) using Form 2: Antimicrobial Susceptibility Testing. For Form 2: Antimicrobial Susceptibility Testing, the annual frequency of responses per respondent is 1,452 (121 isolates x 12 months). Based on previous laboratory experience, the estimated burden of completing Form 2 for each participating laboratory is 1 hour per response, which includes the time required for laboratory

processing of the patient's isolate, gathering and maintaining the data needed, and completing and reviewing the collection of information. For Form 3: Control Strain Susceptibility Testing, a "response" is defined as the processing and recording of Regional laboratory data for a set of seven control strains. It takes approximately 12 minutes to process and record the Regional laboratory data on Form 3 for one set of seven control strains, of which there are 4 sets. The number of responses per respondent is 48 (4 sets x 12 months).

The total estimated annual burden hours are 8,628. Respondents receive federal funds to participate in this project. There are no additional costs to respondents other than their time.

Estimate of Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Clinic	Demographic Clinical Data Form 1	30	240	11/60	1,320
Laboratory	Antimicrobial Susceptibility Testing Form 2	5	1,452	1	7,260
	Control Strain Susceptibility Testing Form 3	5	48	12/60	48
Total					8,628

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Leroy A. Richardson
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention
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