Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-0307]

# Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**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. GISP has tracked penicillin and tetracycline resistance and identified the emergence of fluoroquinolone resistance. 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 5 Regional laboratories receives and processes 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 1452 (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 7 control strains. It takes approximately 12 minutes to process and record the Regional laboratory data on Form 3 for one set of 7 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) |
|---|---|---|---|---|
| Clinic | Demographic Clinical Data Form 1 | 30 | 240 | 11/60 |
| Laboratory | Antimicrobial Susceptibility Testing Form 2 | 5 | 1,452 | 1 |
| | Control Strain Susceptibility Testing Form 3 | 5 | 48 | 12/60 |

_____

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2015-31104 Filed: 12/9/2015 8:45 am; Publication Date: 12/10/2015]