Gonococcal Isolate Surveillance Project

OMB 0920-0307

60 Day Federal Register Notice

Robert Kirkcaldy, Project Officer

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of STD Prevention
Epidemiology and Surveillance Branch
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop E-02
Atlanta, GA 30333

Voice: (404) 639-8659
Fax: (404) 639-8610
Email: hgl8@cdc.gov

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-4604 or send comments to Maryam Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

The Gonococcal Isolate Surveillance Project (GISP, OMB No.0920-0307) – 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 antimicrobial susceptibility of strains of *Neisseria gonorrhoeae* in the United States and (2) to characterize resistant isolates. GISP provides critical surveillance for antimicrobial resistance, allowing for informed treatment recommendations. Monitoring antibiotic susceptibility is critical since *Neisseria gonorrhoeae* has demonstrated the consistent ability to gain antibiotic resistance. 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

isolates per month to the regional laboratories, which measure susceptibility to a panel of antibiotics. Limited demographic and clinical information corresponding to the isolates are submitted directly by the clinics to CDC.

During 1986-2009, GISP has demonstrated the ability to effectively achieve its objectives. The emergence of resistance in the United States to penicillin, tetracyclines, and fluoroquinolones among *Neisseria 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.

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. The estimated time for clinical personnel to abstract data for Form 1 is 11 minutes per response.

Each of the 5 Regional laboratories receives and processes an average of 20 isolates from 6 different clinics per month (i.e. 120 isolates per regional laboratory per month) using Form 2. For Form 2, the annual frequency of responses per respondent is 1440 (120 isolates x 12 months). Based on previous laboratory

experience, the estimated burden for each participating laboratory for Form 2 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, 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). Respondents receive federal funds to participate in this project. There are no additional costs to respondents.

Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Clinic	Form 1	30	240	11/60	1,320
Laboratory	Form 2	5	1,440	1	7,200
	Form 3	5	48	12/60	48
Total		40			8,568

DATE:

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Maryam I. Daneshvar, Ph.D.
Acting Reports Clearance Officer
Centers for Disease Control and Prevention