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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0307]

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 404-639-7570 or send comments to Ron Otten, 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 exp. 12/31/2013) – Revision – National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain Office of Budget and Management (OMB) approval to revise the data collection for the Gonococcal Isolate Surveillance Project (GISP)(OMB No.0920-0307, expires 12/31/2013). CDC seeks a three-year approval to conduct the GISP project. Revisions to this ICR consist of removing 4 variables from the approved Form 1: Demographic and Clinical Data. The variables to be removed have not proven useful in the past and will not increase or decrease the burden. 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. Surveillance of *N. gonorrhoeae* antimicrobial resistance is

important because: (1) nearly all gonococcal infections are treated empirically and susceptibility testing data is not routinely available in clinical practice; (2) *N. gonorrhoeae* has consistently demonstrated the ability to develop resistance to the antimicrobials 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 critical national, regional, and site-specific gonococcal antimicrobial resistance data. 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 susceptibility of the isolates to 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 1986-2012, 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. 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 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). 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	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		40			8,628

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