Gonococcal Isolate Surveillance Project

OMB 0920-0307

Supporting Statement – Part A

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Section A.

Justification.

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs

Section B. Collection of Information Involving Statistical Methods

TABLES

Table 16.A Project Time Schedule

LIST OF ATTACHMENTS

1. Authorizing Legislation - Public Health Service Acts, Section 301 and Section 318
2. 60 Day Federal Register Notice
3. Data Collection Forms
   - 3a. Form 1 - Demographic/Clinical Data
   - 3b. Form 2 - Antimicrobial Susceptibility Testing
   - 3c. Form 3 - Control Strain Susceptibility Testing
4. Screen shots of web-based application
5. IRB Determination
6. Project Personnel
   - 6a. CDC Participants
   - 6b. Sentinel Clinic and Regional Laboratory Address List
7. Sample Report – Gonococcal Isolate Surveillance Project (GISP) Annual Report 2008
8. Data Coding Guide

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, (NCHHSTP), Centers for Disease Control and Prevention (CDC) requests OMB to approve extension of the currently approved version of 0920-0307, Gonococcal Isolate Surveillance Project (GISP), for 3 years.

Approximately 700,000 persons require treatment for gonorrhea each year. Without treatment, gonococcal infections can result in serious sequelae such as pelvic inflammatory disease, infertility, and ectopic pregnancy. Effective gonococcal therapy is complicated by the ability of *Neisseria gonorrhoeae* to develop resistance to antibiotics.

GISP was created in 1986 to the address the problem of changing resistance patterns in *N. gonorrhoeae*. GISP is a unique national sentinel surveillance system that monitors trends in antimicrobial susceptibilities of *N. gonorrhoeae* strains in the United States and plays an integral role in guiding national gonococcal therapies. It is the oldest surveillance system in the United States for monitoring antimicrobial resistance and was identified as a model surveillance system during the July 1999 Interagency Task Force on Antimicrobial Resistance discussions

held in Atlanta, GA that led to the 2001 Public Health Action Plan to Combat Antimicrobial Resistance.

The programs and data collection are authorized by the Public Health Service Act, Sec. 301 and 318 (42 USC 241 and 247c) (Attachment 1).

Privacy Impact Assessment

Overview of the Data Collection System

Local providers obtain urethral isolates of *N. gonorrhoeae* from the first 25 men with urethral gonococcal infection each month. Because there may be occasional month-to-month variability in the number of isolates submitted, a sentinel site may provide more than 25 isolates in any given month to make up for providing less than 25 isolates in other months; the overall goal is for each sentinel site to provide at least 300 isolates per year.

Isolates are frozen until shipped to the Regional Laboratory. Isolates are shipped each month to the Regional Laboratory.

All data from Form 1 (Demographic/Clinical Data), Form 2 (Antimicrobial Susceptibility Testing), and Form 3 (Control Strain Susceptibility Testing) (Attachments 3a, 3b, and 3c), are sent electronically through a secure GISP-web based application that only the sentinel site appointee, regional laboratory manager, GISP data manager, and Project Officer are able to

access. All personal identifying information (e.g., name, address) on individual patients is retained by the local STD clinics and is not collected on GISP data collection forms and is not included with data sent to CDC.

Items of Information to be Collected

No individually identifiable information is collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The project website features information on the history of the project, the most updated OMB-approved protocol, annual reports, Forms 1, 2, and 3 (Form 1: Demographic/Clinical Data; Form 2: Antimicrobial Susceptibility Testing; and Form 3: Control Strain Susceptibility Testing) (Attachments 3a, 3b, and 3c), and the data coding guide (Attachment 8). No data are collected on the website. The website does not contain information or pages directed at children under the age of thirteen years.

2. Purpose of Use of the Information Collection

Because effective treatment of gonococcal infections poses certain challenges, it is essential that the patients and the treatment regimens are monitored. Without GISP data, it would not be possible to know whether antibiotics used to treat gonorrhea remain effective over time. Without that information,

both effective treatment and effective control of gonorrhea transmission would be jeopardized.

In addition, many non-GISP laboratories now use non-culture tests to diagnose gonorrhea; without culture, the organism is not available for antimicrobial resistance testing. Thus, the GISP system fills critical surveillance needs.

Information from GISP is continually used as the basis for revising gonococcal treatment regimens. CDC's Sexually Transmitted Diseases (STD) Treatment Guidelines have been published in 1993, 1998, 2002, 2004, and 2006. GISP data from 2005 to June 2006 indicated increased prevalence of fluoroquinolone-resistant *N. gonorrhoeae* (QRNG) which prompted CDC to revise the treatment recommendations for gonococcal infections. CDC's 2006 Sexually Transmitted Diseases (STD) Treatment Guidelines revised the use of fluoroquinolones in gonococcal disease and CDC published an MMWR article stating that fluoroquinolones were no longer recommended for treatment of gonococcal infections. (1, 2)

CDC's STD Treatment Guidelines are used as the standard of care by publicly funded STD programs and in many other clinical practice settings throughout the United States.

Privacy Impact Assessment Information

No individually identifiable information is being collected or being shared. Data collection will have little to no effect on patients' privacy. The purpose of GISP is to monitor trends in antimicrobial resistance in strains of *N. gonorrhoeae* in the United States in order to establish a rational basis for the selection of gonococcal therapies. Gonococcal isolate properties included in the GISP database are also used by researchers at CDC and outside CDC to better understand the emergence, trends over time, and spread of gonococcal resistance.

3. Use of Improved Information Technology and Burden Reduction

In compliance with the recommendation of OMB per the Notice of Action of the previous approved ICR, all data from Form 1 (Demographic/Clinical Data), Form 2 (Antimicrobial Susceptibility Testing), and Form 3 (Control Strain Susceptibility Testing) (Attachments 3a, 3b, and 3c), are being sent electronically through a secure GISP-web based application. Approximately 100% of the responses are gathered through this option. The remaining respondents report laboratory and patient data through Microsoft Excel spreadsheet. (See Attachment 4 for screen shots of GISP Web application).

4. Efforts to Identify Duplication and Use of Similar Information

The principal investigators and co-investigators (who include notable non-CDC experts in the field, see Attachment 6b) have completed a thorough review of the literature, and there is no similar system to monitor antimicrobial resistance in *N. gonorrhoeae* at the national level.

5. Impact on Small Business or Other Small Entities

No small business or other small entities are involved in this project. Respondents are exclusively local health departments.

6. Consequences of Collecting the Information Less Frequently

Past experience indicates that gonococcal resistance patterns can change relatively rapidly. Therefore, the GISP protocol requests monthly reporting by sentinel STD clinics and laboratories (which are state / local health departments and private labs) in order to:

1) monitor emergence of new antimicrobial resistance or sudden changes in antimicrobial resistance trends; and
2) ease the burden of processing specimens for the participating laboratories. For these laboratories, it is easier to process

isolates on an ongoing basis rather than store, process, and report them on a quarterly or annual basis.

After GISP detects an increase in suspected antimicrobial resistance patterns, appropriate responses (i.e., changes in guidelines, implementation of new therapeutic regimens, etc.) must be developed. Thus, GISP serves as a timely surveillance system that allows for rapid detection and response to new resistance patterns.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day notice to solicit public comments was published in the Federal Register on August 19, 2010, Volume 75, Number 160, pages 51269-51270 (Attachment 2). We received one comment that highlighted the respondent’s belief that this surveillance activity is not worthwhile due to a small number of cases and that this activity should be addressed locally. In contrast to the view of the respondent, CDC has observed that antibiotic

resistance in *N. gonorrhoeae* continues to expand and evolve, requiring ongoing surveillance. Furthermore, local culture and susceptibility capacity and usage in the United State continue to decline. This surveillance system is one of the few remaining robust sources of data on gonococcal susceptibility patterns.

B. GISP is a collaborative project among CDC investigators; non-CDC scientists, five regional laboratories, and 30 sentinel STD clinics located around the United States. (See Attachment 6a & 6b for a list of all those participating in GISP.) CDC has frequent consultations with persons outside CDC regarding the availability of data, frequency of collection, clarity of instructions, and data elements to be recorded has taken place via: 1) site visits to participating sentinel clinics and regional laboratories; 2) annual meetings of GISP co-investigators outside of CDC who are closely associated with the participating laboratories and clinics; and 3) e-mail communications among all personnel participating in GISP activities.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Because no individually identifiable information is being collected, the Privacy Act is not applicable.

Privacy Impact Assessment Information

The urethral gonococcal isolates are collected from patients as part of their routine care after a gonorrhea infection has been diagnosed. A unique number is assigned to each isolate and corresponding patient. Isolates are assigned sequential identifiers for each month. Each record is composed of a three-letter designation for the STD clinic site, followed by a six-digit number indicating the year and month, and a two digit number in the sequence from 01 through 25. Patient data is obtained through review of medical records by the clinic staff and included in Form 1. GISP data collection forms contain no personal identifiers and the data are not linked to specific individuals. All personal identifying information (e.g., name, address) on individual patients is retained by the STD clinics that treated the patient and is not recorded with data sent to CDC.

Completed GISP data collection forms are stored in a locked file cabinet. Only the GISP data manager and project coordinator have access to these data. The electronic GISP database is stored on the CDC mainframe computer and only the Division of STD Prevention (DSTDP) data managers have access rights to the data.

11. Justification for Sensitive Questions

Cases of gonorrhea are routinely reportable in all state health departments, and patient information is routinely collected by state, county, and city health departments' STD program personnel for purposes of disease control. The patient data collected with Form 1 (Attachment 3a) is a subset of this routinely collected information.

The sensitive questions on Form 1 include: sexual preference, the reason for visiting the STD clinic, previous history of gonorrhea, HIV status, travel history, prior antibiotic use, history of giving or receiving drugs or money for sex, and recreational drug use. These are elicited at participating STD clinics in a confidential environment and recorded by STD clinicians in order to assess high risk sexual behaviors and to provide appropriate behavioral counseling; these items are asked for all STD infections and not specifically for GISP. These sensitive questions are essential in order to develop an accurate surveillance picture of disease in the community.

Sexual preference and recreational drug use identify increased risk of gonorrhea, including transmission of resistant strains, in certain sub-populations known to be at high risk for STDs.

Reason for visit is useful for determining which isolates are from previously seen patients. If these isolates make up a large proportion of the sample, the representation of the sample may be adversely affected.

Previous history of gonorrhea for useful in determining whether antibiotic resistance is more likely to emerge in core groups of individuals who have frequent gonococcal infections and are treated with antibiotics frequently.

HIV status is useful for identifying increased transmission of resistant strains among certain immunosuppressed sub-populations who may be engaging in risky sexual behavior.

Travel history, prior antibiotic use, history of giving or exchanging drugs or money for sex, and recreational drug use have all been associated with increased risk for infection with resistant gonorrhea and as risk factors associated with emergence of resistance.

12. Estimates of Annualized Burden Hours and Costs

Under the GISP protocol, sentinel clinics are asked to provide 25 isolates per month (as noted on Forms 1 and Form 2). However, due to low volume at some sites in certain months, we expect an average of 20 isolate submissions per sentinel site per month. This provides an approximate total of 121 isolates to be tested

and recorded per regional laboratory monthly. These estimates are based on the total number of isolates submitted in 2009, and also serve as the basis for calculating burden hours and cost to respondents.

For Forms 1 and 2, a "response" is defined as the data collection/processing and laboratory processing associated with an individual gonococcal isolate from an individual patient. A total of 30 sentinel sites will submit 20 isolates on a monthly basis or 600 responses annually, via Form 1. The estimated time for clinic personnel to abstract data for Form 1 is 11 minutes per response (Attachment 3a).

Five regional laboratories will provide 121 isolates each month or 1,452 responses annually via Form 2. Based on previous laboratory experience in analyzing gonococcal isolates, the estimated time for each participating laboratory to record data on Form 2 is 1 hour per response and 7,260 hours for all 5 laboratories annually (Attached 3b).

For Form 3, a "response" is defined as the testing and recording of Regional laboratory data for a single control strain set. Each Regional laboratory submits data for 4 sets of 7 control strains each month or 48 sets of control strains annually (4 sets x 12 months = 48). It takes approximately 12 minutes to process 1 set of 7 control strains and to record the data on Form

3. The annual burden to collect data using Form 3 is 48 hours (Attachment 3c). Thus, the estimated annualized burden for all 3 data collection methods is 8,628 hours.

Table 12A: Estimated Annualized Burden Hours and Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours
Clinic	Form 1	30	240	11/60	1,320
Laboratory	Form 2	5	1,452	1	7,260
	Form 3	5	48	12/60	48
Total		40	1740		8,628

We anticipate use of the GISP software and web application discussed in Item A.3 during this approval period which reduces the burden required for clinic respondents using Form 1. However, since there is no mandatory requirement for their use, the time to record responses manually was used to calculate the burden.

Costs to respondents are incurred in purifying, storing and forwarding isolates to regional laboratories; transferring data from medical records to GISP forms; entering the data into an electronic database locally (some clinics are currently not able to do this); and forwarding the information to CDC.

All respondents are paid through federal funds so there is no additional cost to them to provide the isolates and complete Forms 1 to 3. However, in order to calculate the cost to the respondents, we use the hourly wage rate for a clerk at the clinic and a lab technician from the U.S. Office of Personnel Management, 2007 General Schedule including Locality Rates of Pay for Atlanta, GA.

Table 12.B.Estimated Annualized Costs

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clinic	30	240	11/60	1,320	$16.13	$21,291.60
	5	1,452	1	7,260	$19.98	$145,054.80
Laboratory	5	48	12/60	48	$19.98	$959.04
Total	40	1,740		8,628		$167,305.44

* Respondents are paid through federal funds from the CDC Comprehensive STD Prevention Systems, Prevention of STD-Related Infertility, and Syphilis Elimination Grant (CSPS).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

None.

14. Annualized Cost to the Federal Government

Table A.14: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Data Manager (GS-13, .5 FTE)	$46,000
	CDC Laboratory Personnel (GS-15, .05 FTE)	$6,000
	CDC Laboratory Personnel (GS-13, .10 FTE)	$8,000
	CDC Laboratory Personnel (GS-12, .20 FTE)	$12,000
	CDC Laboratory Personnel (GS-11, .6 FTE)	30,000
	CDC Laboratory Personnel (GS-9, .7 FTE)	$27,000
	CDC Epidemiologist (GS-15, .7 FTE)	$65,100
	CDC Project Coordinator (GS-11, .7 FTE)	$38,500
	Subtotal, Direct Costs to the Government	$ 232,600
Travel and other related expenses	Travel, supplies, and annual GISP report	$ 54,300
	Subtotal, Travel and other project-related expenses	$ 54,300
Federal Grant	CDC Comprehensive STD Prevention Systems, Prevention of STD-Related Infertility, and Syphilis Elimination Grant for GISP collaborators	$ 520,000
	Subtotal, Federal Grant	$520,000
	TOTAL COST TO THE GOVERNMENT	$806,900

The total annualized cost to the government is $806,900. The total cost to the government over the 3-year period is $2,420,700.

15. Explanation for Program Changes or Adjustments

There are a total of 5 regional labs. The regional laboratory in Denver, CO has been replaced by a regional lab in Austin, TX.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A.16: Project Time Schedule

Activity	Time Schedule
Collection of isolates and clinical/demographic data from sentinel STD clinics	Monthly after OMB approval for 3 years
Processing and testing of isolates at regional labs	Monthly after OMB approval for 3 years
Download data from GISP Web or collection of paper forms from clinics and laboratories to CDC	Quarterly after OMB approval for 3 years
Data management and validation of data collected	Quarterly after OMB approval for 3 years
Dissemination of results via annual report	12 months after OMB approval and annually for 3 years

Preliminary data analysis is expected to begin 4 – 6 months after OMB approval and final data analysis is expected to be completed 12 months after OMB approval. Data analyses include descriptive analyses and trends in gonococcal antimicrobial resistance over time. Trends are presented as a percentage of isolates which are resistant to specific antimicrobial agents. Summary tables of demographic/clinical characteristics by antimicrobial resistance

patterns are calculated. A complete annual report is distributed to participating clinics and regional laboratories by CDC (Attachment 7). Brief summary reports of the GISP data are included in routine surveillance reports published by CDC. In addition, analyses of the data are published in scientific and public health journals and presented at scientific meetings. The information from these reports of the GISP data are used by CDC, state and local STD program managers for program planning and resource allocation; non-STD program policy makers; clinical and laboratory researchers; and others (Attachment 6 for list of all GISP participants).

17. Reason(s) Display of OMB Expiration Date is Inappropriate

This project is not requesting exemption of the expiration date being displayed on the forms.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

There are no exceptions to the certification.

References

1. CDC. 2006 Sexually Transmitted Diseases Treatment Guidelines. MMWR 2006; 55(No. RR-11).

2. CDC. Update to CDC's *Sexually Transmitted Diseases Treatment Guidelines, 2006*: Fluoroquinolones No Longer Recommended for Treatment of Gonococcal Infections. MMWR. April 13, 2007/56(14); 332-336.