Gonococcal Isolate Surveillance Project

OMB 0920-0307

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TABLE OF CONTENTS

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
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

B. Collection of Information Involving statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Test of Procedures or Methods to Be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

TABLES

LIST OF ATTACHMENTS

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 approval for 3-years to implement a revised version of 0920-0307, Gonococcal Isolate Surveillance Project (GISP). There are two changes currently incorporated into the revised version for this ICR: 1) in compliance with the recommendation of OMB per the Notice of Action of the previous approved ICR, all data from Form 2 (Demographic/Clinical Data) and Form 3 (Antimicrobial Susceptibility Testing) are being sent electronically through a GISP-web based application and Form 1 (Control Strain Susceptibility Testing) is being developed under the same web-based application; and 2) the increase of three sentinel sites and the decrease of one. The contributions by the additional sentinel sites added to GISP will reflect an increased in burden (See Item A.15).

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* and is a unique national sentinel surveillance system that monitors trends in antimicrobial susceptibilities of strains of *N. gonorrhoeae* in the United States and plays an integral role in guiding national gonococcal therapies(1). 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).

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.

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.

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, and 2004. 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. In the 2006 CDC's Sexually Transmitted Diseases (STD) Treatment Guidelines revised the use of fluoroquinolones in gonococcal disease and published an MMWR article stating the CDC no longer recommended fluoroquinolones for treatment of gonococcal infections (2,3).

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. GISP data 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 order to decrease the respondent burden and facilitate completion, CDC has developed and distributed data entry software (Epi Info) to participating sites to facilitate data entry and local data analysis on Form 1. The use of this software is optional and left up to the convenience of the respondent. Approximately 40% of the responses are gathered through this option. The remaining respondents report laboratory and patient data through the paper versions of Form 1.

In addition as required by OMB (1/18/2005) this revision incorporates increased use of electronic versions of Forms 2 and 3. In addition, CDC has developed, GISP Web, a web-based application to streamline GISP data processing and reduce data entry errors. Currently, Form 2 and Form 3 have been developed for use in GISP Web and are being utilized by all 5

GISP regional labs. Form 1 is still under development in GISP Web and should be available by September 2007. We estimate that 93% would utilize this option. (See Attachment 3 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 4b) 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. 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.

5. Impact on Small Business or Other Small Entities

No small business or other small entities are involved in this project. Physicians in private practice report sexually transmitted diseases encountered in their practices to the local health department as required by state and national regulations.

6. Consequences of Collecting the Information Less Frequently

The GISP protocol requests monthly reporting by sentinel STD clinics and laboratories in order to:

1) monitor emergence of new antimicrobial resistance or sudden changes in antimicrobial resistance trends. Past experience indicates that gonococcal resistance patterns can change relatively rapidly; 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.

Finally, after GISP detects changes in resistance patterns, time is needed to develop appropriate responses, i.e., changes in guidelines, implementation of new therapeutic regimens, etc. Thus, a timely surveillance system is necessary to allow 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

The monthly reporting remains unchanged from the previously approved ICR (0920-0307 Expiring January 31, 2008). Respondents are requested to report gonococcal isolates each month rather than on a quarterly basis or less frequently for the reasons stated in item 6 above.

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

A 60-day notice to solicit public comments was published in the Federal Register on June 28, 2007, Volume 72, Number 124, pages 35490-35491 (Attachment 5). Two public comments were sent by same person. These comments and CDC response to both the comments are in Attachment 6.

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 4a & 4b 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

None

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Administrator has reviewed this project and has determined that the Privacy Act is not applicable.

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. The GISP isolates are collected from patients as part of their routine care. 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 and is not recorded with data sent to CDC.

Completed GISP data collection forms are stored in a file cabinet with a lock. 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. Occasionally, GISP data are stored on the password-protected personal computer of the GISP data manager at CDC and is protected by the security protocols of the agency including a strong firewall.

11. Justification for Sensitive Questions

Cases of gonorrhea are routinely reportable in all state health departments, and patient information is routinely collected by state and county or city health departments' STD program personnel for purposes of disease control. The patient data collected with Form 1 (Attachment 2a) 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 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 not asked specifically for GISP. These items are essential in order to develop an accurate surveillance picture of disease in the community.

Sexual preference and recreational drug use identify increased transmission of resistant strains in certain sub-populations known to be at high risk for STDs.
Reason for visit is useful in 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 is 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 in 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. It is important to monitor trends in these 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 clinic per month. This provides a 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 2006, 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 laboratories will submit 20 isolates on a monthly basis or 240 responses annually, via Form 1. The estimated time for clinic personnel to abstract data for Form 1 is 11 minutes per response (Attachment 2a).

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 2b).

For Form 3, a "response" is defined as the testing and recording of laboratory data for a single control strain set. Each laboratory submits data for 4 sets of 7 control strains each month or 48 control strains annually. It takes approximately 12 minutes per run of 7 control strains in each set and to record the data on Form 3. Thus the annual burden

to collect data using Form 3 is 48 hours (Attachment 2c). 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 Annual Burden (in 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			8,628

We anticipate incremental use of the GISP software and web application discussed in Item A.3 during this approval period which could reduce 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	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)	Average Hourly Wage Rate	Total Annual Respondent Cost
Clinic	Form 1	30	240	11/60	1,320	$16.13	$21,291.60
Laboratory	Form 2	5	1,452	1	7,260	$19.98	$145,054.80
	Form 3	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	$ 520,000

	Elimination Grant for GISP collaborators	
	Subtotal, Federal Grant	$520,000
	TOTAL COST TO THE GOVERNMENT	$806,900

15. Explanation for Program Changes or Adjustments

We added 3 additional clinics in the past 3 years and lost 1 site, for a total of 30 sites in 2007. There has been an increase in the average number of isolates submitted monthly (from 19 in 2003 to 20 in 2007). Because of the current additions the burden for this ICR has an increase of 486 hours of burden.

16. Plans for Tabulation and Publication and Project Time Schedule

GISP has been a successful surveillance system since 1986 and has already demonstrated its feasibility and usefulness. Since GISP is a long term surveillance system, it is expected that data collection will continue until a better system can be devised or in the unlikely event that gonorrhea incidence decreases to a point where the disease is no longer a significant public health problem.

Therefore, the maximum duration of 3 years OMB clearance is requested.

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 4 for list of all GISP participants).

The project time schedule for GISP is shown in Table A.16.

Table A.16: Project Time Schedule

Activity	Time Schedule Year 1	Time Schedule Year 2	Time Schedule Year 3
Collection of isolates and clinical/demographic data from sentinel STD clinics	Monthly after OMB approval	Monthly after OMB approval	Monthly after OMB approval
Processing and testing of isolates at regional labs	Monthly after OMB approval	Monthly after OMB approval	Monthly after OMB approval
Download data from GISP Web or collection of paper forms from clinics and laboratories to CDC	Quarterly after OMB approval	Quarterly after OMB approval	Quarterly after OMB approval
Data management and validation of data collected	Quarterly after OMB approval	Quarterly after OMB approval	Quarterly after OMB approval
Preliminary data analysis	4 – 6 months after OMB approval	16 – 18 months after OMB approval	28 – 30 months after OMB approval
Final data analysis	12 months after OMB approval	24 months after OMB approval	36 months after OMB approval
Dissemination of results via annual report	12 months after OMB approval	24 months after OMB approval	36 months after OMB approval

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

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

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

No special exceptions to certification apply

References

1. CDC. Special focus: Surveillance for sexually transmitted diseases. MMWR. August 13,1993/42(SS-3);29-39.

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

3. 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.