

**Gonococcal Isolate Surveillance Project**

**OMB 0920-0307**

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**Supporting Statement - Part B**

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## **GONOCOCCAL ISOLATE SURVEILLANCE PROJECT**

**0920-0370**

### **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 No Response
4. Tests of Procedures or Methods to Be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

## 1. Respondent Universe and Sampling Methods

The respondent universe includes 30 sentinel STD clinics, which collect and enter data on Form 1, and the 5 regional laboratories which collect and enter data on Forms 2 & 3.

GISP is based on sentinel surveillance because the logistics of doing standardized, antimicrobial susceptibility testing for multiple antibiotics on a random sample of patients from the community over time would be extremely difficult, costly, and inappropriate for a long-term surveillance system.

Sentinel clinics and laboratories voluntarily apply to participate and are selected on the basis of the following criteria: willingness and ability to participate, location (e.g., an area with no other GISP site, high gonorrhea incidence, and strategic importance [resistance in the United States tends to emerge first in the West]), and expertise with antimicrobial susceptibility testing of *Neisseria gonorrhoeae*.

There is no specific statistical sampling method used to select the clinics or laboratories, because comparisons of the pooled data from GISP have correlated well with the national data collected on the following factors: penicillinase-producing *N. gonorrhoeae* (PPNG), demographic characteristics (age, race) of patients with PPNG, and

trends and geographic distribution of PPNG. These comparisons indicate that the 30 sites represent the nation as a whole (CDC, unpublished data).

Within each sentinel clinic site, under the GISP protocol, the first 25 gonococcal isolates from male urethral cultures each month are selected. This sampling method was chosen because a 1985-1986 study in a clinic where laboratory testing was available on all isolates for a period of many months showed this sampling method to be representative of the predominant isolates in the clinic population. (1) Because of low volume at some sites, clinics submit an average of 20 isolates per clinic per month. Low volume sites have been kept as a part of GISP because many are in geographically strategic locations and others serve unique populations.

## **2. Procedures for the Collection of Information**

Isolates for laboratory analysis are collected from male patients with symptoms of gonococcal disease, as part of routine clinical care. Examination, testing, and treatment are provided to patients according to the routine procedures in the participating STD clinics.

Information for GISP is collected on 3 forms, Forms 1, 2, & 3 (Attachment 3a - 3c [3c1&3c2]). The procedures for each form are as follows:

Form 1 (Attachment 3a): Each month, sentinel clinics submit urethral gonococcal isolates from men to their assigned GISP regional laboratories. This usually starts on the Monday of the first full week each month. Clinical/demographic data on the patient providing the isolate is included in Form 1. Laboratories are directed to collect isolates from the first 25 male patients with positive urethral gonococcal cultures seen at each participating sentinel clinic. However, due to the variability in number of patient visits to sentinel clinics, a monthly average number of 20 isolates per month per laboratory is used to calculate the burden and cost to respondents. Clinical/demographic data on these patients are abstracted by clinic personnel from patient medical records. No personal identifiers (name, address, etc.) are collected for entry into GISP. These data are entered on Form 1 (Attachment 3a). Data are transmitted to CDC via the GISP web-based application.

Forms 2 & 3 (Attachments 3b & 3c[3c1&3c2]): All isolates from the sentinel clinics are tested at the regional laboratories for susceptibility to a specified panel of

antimicrobials using a standardized procedure. Once laboratory testing is completed, susceptibility data on each isolate are entered on Form 2 (Attachment 3b), control strain data on Form 3 (Attachment 3c [3c1 & 3c2]), and the data are transmitted to CDC via the GISP web-based application.

Patients found to have resistant isolates are treated and managed according to the STD clinic's routine for other patients with resistant isolates.

Data from all forms arriving at CDC are logged, edited, and entered into the databases for computer processing and analysis. An annual report sent to all clinics and laboratories includes a summary of the data and displays trends with preceding years. These reports and tables are used to provide feedback to sites on the timeliness and quality of data. In addition, CDC personnel visit each GISP site as needed to resolve issues that may arise.

### **3. Methods to Maximize Response Rates and Deal with No Response**

Currently, 100% of the clinics and laboratories participating in GISP submit data monthly. The high response rate is attributable to the high interest of respondents in GISP. Site visits and frequent communication between the

data manager and individuals responsible for reporting have also contributed to the 100% response rate.

#### **4. Test of Procedures or Methods to Be Undertaken**

Diagnostic tests for gonococcal disease have been previously approved by OMB and there are no changes. Each laboratory is required to adhere to a standard protocol for agar dilution antimicrobial susceptibility testing as indicated by the GISP protocol and demonstrate the ability to maintain the standards of quality assurance by participating in bi-annual external quality assessment testing.

The method used for agar dilution susceptibility test, antimicrobial susceptibility panel and use of control specimens have been set forth by the CDC Gonorrhea Reference Laboratory, Atlanta, GA and have been used since 1986.

#### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and /or Analyzing Data**

Data collection and management is performed by:

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Please see **Attachment 6b** for list of all individuals from the sentinel clinics and regional laboratories that collect data for GISP.

### **References**

1. Rice RJ, Hook EW III, Holmes KK, Knapp JS.  
Evaluation of sampling methods for surveillance of *Neisseria gonorrhoeae* strains populations. 167-173.  
In. Gonococci and Meningococci. J. T. Poolman (ed.).  
Kluwer Academic Publishers, Dordrecht, 1986.