Gonococcal Isolate Surveillance Project

OMB 0920-0307

Supporting Statement – Part B

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June 13, 2013

B. Collection of Information involving Statistical Methods

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 a sentinel surveillance system approach 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 are selected on the basis of the following criteria: willingness and ability to participate, location (e.g., an area with no other GISP site and high gonorrhea incidence), 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comparisons indicate that the 30 sites represent the nation as a whole (CDC, unpublished data).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 urethral cultures obtained from men each month are selected. This sampling method was chosen because a 1985-1986 study 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 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). 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 are included in Form 1. Sentinel clinics and laboratories are directed to collect isolates from the first 25 male patients with positive urethral gonococcal cultures seen at each participating sentinel clinic each month. 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 secure GISP web-based application or directly to the GISP data manager at CDC.

Forms 2 & 3 (Attachments 3b & 3c): All isolates from the sentinel clinics are tested at the regional laboratories for susceptibility to a specified panel of antibiotics using a standardized procedure. Once laboratory testing is completed, patient isolate data are entered on Form 2 (Attachment 3b), control strain data on Form 3 (Attachment

3c), and the data is 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 or communicate with each GISP site at least once in three years or as needed to resolve issues that may arise.

3. Methods to Maximize Response Rates and Deal with Nonresponse

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 near 100% response rates.

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 methods used for agar dilution susceptibility testing, including antibiotic 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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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.