

Gonococcal Isolate Surveillance Project

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Supporting Statement - Part B

REVISION

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GONOCOCCAL ISOLATE SURVEILLANCE PROJECT

0920-0370

B. Collection of Information Involving Statistical Methods

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1. Respondent Universe and Sampling Methods

The respondent universe includes 4 regional laboratories and 40 sentinel sites (i.e., STD clinic or multiple STD clinics affiliated with a single public health department); of the 40 sentinel sites, 20 sites will conduct core culture-based surveillance activities only, 10 sites will conduct core and enhanced culture-based surveillance activities, and 10 sites will conduct enhanced molecular surveillance activities.

GISP is based on sentinel surveillance because the logistics of doing standardized, antimicrobial susceptibility testing or molecular testing for multiple antibiotics and mutations 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 sites 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 sentinel sites 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comparisons indicate that it is reasonable that the culture-based GISP sites represent the nation as a whole (CDC, unpublished data).

Within each sentinel site performing culture-based surveillance, 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. Additionally, in the ten clinics that voluntarily participate in enhanced culture-based surveillance activities in addition to core activities, additional isolates are collected from women with symptoms of gonorrhea or who are contacts to gonorrhea and from men and women who have presumed or confirmed gonorrhea in the pharynx or rectum. This sampling methodology was chosen because it efficiently builds upon existing STD clinic and laboratory infrastructure and existing STD clinic screening processes.

Ten sentinel sites participate in molecular surveillance of antimicrobial resistance by testing remnant nucleic acid amplification test (NAAT) specimens collected as part of routine care to diagnose gonorrhea. These sites are asked to retain, freeze and then ship the leftover sample after positive gonorrhea diagnostic results have been determined and reported (remnant NAAT specimens). Sites participating in molecular surveillance are asked to provide up to 70 remnant NAATs per month. Sites will either contribute remnant NAATs from up to the first 25 gonorrhea positive male urethral samples per month (N=5 sites) or 25 gonorrhea positive male genital, 25 female genital, and 25 male or female extragenital samples per month (N=5 sites). Given the variability at collection sites, all molecular surveillance sites will contribute up to 70 remnant NAAT specimens per month. This sampling methodology, similar to culture-based surveillance, was chosen because it efficiently builds upon existing STD clinic and laboratory infrastructure and existing STD clinic screening processes.

On average, each sentinel site that participates in core surveillance will submit 240 isolates per year, each sentinel site that participates in culture-based enhanced surveillance will submit 840 isolates per year, and each sentinel site that participates in molecular enhanced surveillance will submit up to 840 isolates per year (see Table B-1.1).

For all culture-based sentinel surveillance sites, the estimated total number of isolates processed per year is 13,200. We used this number to calculate the estimated annualized number of isolates processed by each of the 4 regional laboratories (3,300 isolates per lab per year; see Table B-1.2). The molecular surveillance samples are sent directly to CDC and are not processed by the regional laboratories. We estimate that 8,400 remnant NAAT specimens

will be sent directly to CDC for testing and will not contribute to the annualized number of samples processed by the regional labs.

Table B-1.1: Estimated Average Number of Isolates Processed by Each Sentinel Site, per Month and Year

Type of Site	No. Isolates per Month	No. Isolates per Year
<i>Culture-based surveillance</i>		
Core activity	20	240
Enhanced activity	70	840
<i>Molecular surveillance</i>		
Enhanced activity	70	840

Table B-1.2: Estimated Average Number of Isolates Processed by Regional Laboratories, per Month and Year

Type of Sentinel Site	No. Sites	No. Isolates/Samples per Site per Month	Total No. Isolates/Samples per Month (All Sites)	Total No. Isolates/Samples per Year (All Sites)	Average No. Isolates/Samples Processed by Each Regional Lab per Year
<i>Culture-based surveillance</i>					
Core Activity	20	20	400	4,800	1,200
Enhanced Activity	10	70	700	8,400	4,200
Total	30	-	1,100	13,200	3,300
<i>Molecular surveillance</i>					
Enhanced Activity	10	70	700	8,400	-
Total	10	-	700	8,400	-

2. Procedures for the Collection of Information

GISP Isolates and remnant NAAT specimens for laboratory analysis are collected from patients with confirmed or presumed 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. Isolates collected for culture-based surveillance in the sentinel sites are sent to regional laboratories for antimicrobial susceptibility testing and results are provided in a standardized format (**Attachment 3b**). Remnant NAAT specimens are sent directly to CDC for testing and determination of known resistance-conferring mutations and results are provided in a standardized format. All GISP sentinel sites provide clinical and demographic data based on data abstracted from patient medical records (**Attachment 3a1/3a2**).

For clinics participating in core activities, isolates are collected from the first 25 male patients with positive urethral gonococcal cultures. However, due to the variability in number of patient visits to sentinel clinics, a monthly average number of 20 isolates per month per sentinel site is used to calculate the burden and cost to respondents. Isolates are batched and submitted to the regional laboratory monthly, usually on the Monday of the first full week each month following isolate collection.

For clinics participating in enhanced culture-based activities, in addition to male urethral isolates collected as part of the core activities, isolates are also collected from the additional patients with confirmed or presumptive gonococcal infection (i.e., women with cervicitis or who are contacts to gonorrhea and men and women who are found to be infected at extragenital sites). A monthly average number of 70 isolates per month per sentinel site is used to calculate the burden and cost to respondents. Isolates are batched and submitted to the regional laboratory monthly, usually on the Monday of the first full week each month following isolate collection.

For clinics participating in enhanced molecular surveillance, gonorrhea-positive remnant NAATs are collected from the first 25 male genital (urethral) only per month, or the first 25 male genital (urethral), the first 25 female genital (endocervical or vaginal) and the first 25 male or female extragenital (pharyngeal or rectal) seen and diagnosed in clinic each month. Due to some variability at each sentinel site, a monthly average of up to 70 remnant NAAT specimens per month per sentinel site is used to calculate the burden and cost to respondents.

At the regional laboratory, antimicrobial susceptibility testing is performed on *N. gonorrhoeae* isolates for a specified panel of antimicrobials using a standardized procedure. Test results are abstracted from the laboratory's

electronic laboratory information system and a comma-separated values (csv) file (**Attachment 3b**) is populated. The csv file (**Attachment 3b**) is submitted electronically by the regional laboratory to CDC through a secure data portal.

For all GISP activities, both core and enhanced activities, clinical/demographic data on patients submitting isolates are abstracted by clinic personnel at the sentinel site from patient medical records. No personal identifiers (name, address, etc.) are abstracted. For the 20 sentinel sites participating in only core activities, these clinical/demographic data are entered into the GISP web-based application (**Attachment 3a1**) and transmitted to CDC electronically. For the 10 sentinel sites participating in culture-based core and enhanced activities or the 10 sentinel sites participating in molecular enhanced activities, a csv file (**Attachment 3a2**) is populated with these clinical/demographic data. These data are either sent directly from the sentinel site to the GISP data manager at CDC through a secure data portal or through the CDC Secure Access Management Services partner portal.

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

Data received at CDC are logged, edited, and transferred into the secure 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 sentinel sites 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, useful information that is regularly shared by CDC with the sentinel sites and laboratories, and excellent working relationship that CDC has established with the clinics and laboratories. 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.

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.

The CDC laboratory and Research Branch will perform testing for molecular evaluation for sites contributing to molecular surveillance. Extraction of genetic material, purification of genetic material, polymerase chain reaction and identification of known antimicrobial resistance-conferring gene mutations will be performed by published and standardized protocols in Atlanta, GA.

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 a 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.