

**Strengthening United States Response to Resistant Gonorrhea (SURRG)**

**OMB 0920-new**

**Supporting Statement – Part B**

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# Strengthening United States Response to Resistant Gonorrhea Project

0920-NEW

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## 1. Respondent Universe and Sampling Methods

The Strengthening United States Response to Resistant Gonorrhea (SURRG) project is a network of 9 collaborating grantees (local health departments or state/local health department pairs) that will serve as a platform to enhance surveillance of *Neisseria gonorrhoeae* antibiotic resistance, rapidly identify antibiotic-resistant gonorrhea, and perform rapid field investigations to halt or slow the spread of identified resistant infections. Collected data will be used to identify and monitor resistance trends, evaluate the effectiveness of public health approaches, and provide an evidence base for the development of novel and impactful gonorrhea prevention strategies.

These collaborating jurisdictions voluntarily applied to participate and were selected on the basis of the following criteria: willingness and ability to participate, location (e.g., high gonorrhea incidence and strategic importance), and expertise with culture testing of *Neisseria gonorrhoeae*.

### *Facility-based gonorrhea data:*

The respondents providing information for SURRG's facility-based surveillance are (1) local SURRG data managers and (2) clinic data managers in participating non-STD clinic health centers. Within the respondent universe of 9 jurisdictions, there are ~27 facilities: 9 STD clinics and 18 partnering healthcare facilities. All case visits for patients tested with gonorrhea will be included in the project and reported to CDC by the collaborating jurisdictions. As part of routine patient care, information on demographics, limited

behavioral risk factors, and details about the clinical encounter (such as laboratory test results and treatment) will be collected by clinic staff and entered into the patient's health record. Every other month, clinic staff from the participating health centers will then abstract data from routine electronic medical records, and transmit to the local SURRG data manager within the jurisdiction.

Laboratory-based data:

Laboratory data on antibiotic resistance testing results of specimens from persons included in the SURRG dataset will be sent directly from the local public health laboratory data management staff to the local SURRG data manager within the jurisdiction.

*Field-investigation gonorrhea data:*

The respondents providing information for SURRG's field investigations are persons interviewed during a gonorrhea field investigation in those collaborating sites. Field investigations will begin by interviewing patients found to have gonorrhea that is antibiotic-resistant or of other public health importance. We anticipate that each site will identify approximately 4 such infections monthly. During the investigation, trained public health officials will attempt to contact and interview contacts of the index case patients and sexual contacts of the index case's contacts. We anticipate that each investigation will yield approximately 6 additional interviews. Each jurisdiction will conduct approximately 120 interviews annually, for a total of approximately 1080 annually across all sites. Data collected on completed interviews will include basic

demographics, medical history, healthcare seeking behavior, sexual behaviors, as well as sexual risk-related information about recent sexual partnerships.

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

### *Facility-based gonorrhea data:*

Every other month, clinic staff at each facility or network of facilities participating in SURRG will abstract and electronically transmit clinical data from all patients tested for gonorrhea at participating clinics to the local SURRG data manager in the jurisdiction (at the local or state health department). SURRG project staff in the jurisdiction will de-identify, clean, recode, and transmit these data to CDC through a secure access management system (SAMS). None of the data transmitted to CDC will contain any personally identifiable information. All project data will be stored and maintained at CDC by a data manager in the Surveillance and Data Management Branch of the Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Data elements collected in this facility-based STD surveillance include patient demographics, limited behavioral risk factors associated with STDs, clinical history and physical exam findings, STD laboratory test results, and dispensed treatments (see Attachments 3A–3D). These clinical data elements were developed collaboratively and agreed upon by members of SURRG from all 9 participating jurisdictions, and are a subset of data elements that participating health centers routinely collect as part of clinical care. CDC staff will routinely monitor completeness of reporting and the quality of data submitted. Site visits, regular communication with CDC, data quality checks and

technical assistance will also provide opportunities for evaluation and troubleshooting of these processes.

*Laboratory-based data:*

Public health laboratory microbiologists will conduct antibiotic susceptibility testing of *Neisseria gonorrhoeae* culture specimens. Data managers from the local public health laboratory will abstract and electronically transmit antibiotic susceptibility data to the local SURRG data manager.

*Field-investigation gonorrhea data:*

Persons found to have a gonococcal infection that is antibiotic-resistant or of other public health importance will be identified through local laboratory testing and interviewed by health department staff (either by telephone or in-person) trained to conduct STD field investigations and partner services. Interviewers will collect information on demographics, STD clinical history, healthcare seeking behaviors, behavioral risk factors associated with STDs, and recent partners and contacts (see Attachment 3D). The entire interview is expected to last for approximately 30 minutes.

These data elements were developed collaboratively by SURRG participating jurisdictions and CDC.

Interview data will be maintained in electronic format by the collaborating jurisdictions.

Every other month, the local SURRG data manager will abstract, clean, de-identify, recode, and transmit data to CDC through a secure access management system (SAMS).

At CDC, data will be downloaded from SAMS, stored, and maintained by a data manager in the Surveillance and Data Management Branch of Division of STD Prevention,

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC. Site visits, regular communication with CDC, data quality checks and technical assistance will also provide opportunities for evaluation and troubleshooting of these processes.

Data on race and ethnicity will be collected in compliance with the two-question format described in the 1997 Office of Management and Budget's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, also known as Statistical Policy Directive 15.

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

#### *Facility-based gonorrhea data:*

Facility data for SURRG are extracted from data collected as a routine part of all STD facility encounters. The challenge of non-response is not applicable for this component of the project because the clinical data elements to be extracted are collected as a routine part of clinical care.

#### Laboratory-based data collection:

Laboratory results will be generated as part of the routine laboratory responsibilities.

The challenge of non-response is not applicable for this component because the laboratory data to be extracted are generated as a part of routine laboratory responsibilities.

#### *Field investigation gonorrhea data:*

Field investigators have all received specialized training in contacting and interviewing persons diagnosed with STDs. These highly trained STD field investigators from

participating jurisdictions will contact patients and contacts who were potentially exposed to gonorrhea in the clinic to complete a phone or in-person interview. Protocols for maximizing the likelihood of a successful interview with patients and potentially exposed contacts vary by site, but at least three attempts to contact a person will be made in all sites. Persons participating in the interview will not be offered reimbursement for their participation, and will be informed that participation in the interview is voluntary and that refusal to participate is at no risk or harm to them. If local regulations offer additional partner management services for patients with gonorrhea, then the patient will be referred accordingly. Similar field investigation interviews have been conducted for other disease control activities, and are part of routine STD control activities in some participating jurisdictions. Non-response rates or patient refusals to be interviewed often vary by jurisdiction and investigator, but have historically been low.

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

##### *Facility-based and laboratory-based gonorrhea data:*

SURRG will collect the results of the following gonorrhea diagnostic tests and laboratory methods: bacterial cultures, nucleic acid amplification tests, and antibiotic susceptibility tests. Use of each of these tests and methods are a part of routine clinical care, and all have been validated by the local public health laboratories as required by relevant laboratory oversight authorities.

##### *Field investigation gonorrhea data:*

The SURRG field investigation interview form was developed using questions from the CDC STD Interview Record, CDC's STD Surveillance Network, collaborating jurisdiction investigation forms, previous CDC surveillance projects, literature on antibiotic resistant *N. gonorrhoeae*, and guidance provided by CDC's *Cephalosporin-Resistant Neisseria gonorrhoeae Public Health Response Plan*. Collaborating jurisdictions have reviewed the interview form extensively for internal consistency and clarity of language.

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

### **Analyzing Data**

Data collection and management at CDC will be performed by:

LaZetta B. Grier  
Data Manager  
Data Management Team  
SDMB, DSTDP, NCHHSTP, CDC  
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SURRG Project Officer/Epidemiologist  
Epidemiology Research Team  
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Data analysis at the CDC will be performed by:

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Chief  
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Local data management and analysis will be conducted at each of the SURRG Grantee Jurisdictions and/or local health departments, including:

- 1) San Francisco Department of Public Health, and California Department of Public Health
- 2) Denver Public Health, and Colorado Department of Public Health and Environment
- 3) Fulton County Department of Health and Wellness, and Georgia Department of Public Health
- 4) City & County of Honolulu, and Hawaii State Department of Health
- 5) Marion County Public Health Department, and Indiana State Department of Health
- 6) Guilford County Department of Health and Human Services, and North Carolina Division of Public Health
- 7) New York City Department of Health & Mental Hygiene
- 8) Public Health – Seattle and King County, and Washington State Department of Health
- 9) Milwaukee Health Department, and Wisconsin Division of Public Health