Strengthening United States Response to Resistant Gonorrhea (SURRG)

OMB 0920-1242

Supporting Statement – Part B

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1. Respondent Universe and Sampling Methods

The Strengthening United States Response to Resistant Gonorrhea (SURRG) project is a network of 8 collaborating grantees (local health departments or state/local health department pairs) that serves 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 are 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.

Collaborating jurisdictions voluntarily applied to participate and were selected on the basis of the following criteria: strength of the application, 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 8 jurisdictions, there will be ~38 facilities: 16 STD clinics and 26 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) are collected by clinic staff and entered into the patient's health record. Every other month, clinic staff from the participating health centers abstract data from routine electronic medical records, and send the data 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 are 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 begin by interviewing patients found to have gonorrhea that has reduced antibiotic susceptibility or of other public health importance. Each site identifies approximately 4 such infections monthly. During the investigation, trained public health officials attempt to contact and interview sexual contacts. We have found that each investigation will yield approximately 6 additional interviews. Each jurisdiction will conduct approximately 120 interviews annually, for a total of approximately 960 annually across all sites. Data collected on completed interviews will include basic demographics, medical history, healthcare seeking behavior, and sexual behaviors. If clinic closures and health department staffing challenges due to COVID-19 continue into late 2021, then participating state and local health departments might face challenges collecting the requested data. CDC will work with the participating health departments

in a collaborative manner to maximize accomplishment of project objectives while also respecting local and state health department capacity. All participating health department staff will follow all relevant local, state, or/and federal COVID-19-related guidance pertaining to social distancing, face coverings, and other recommended measures to protect participants.

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 abstract and electronically send 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 de-identify, clean, re-code, and send these data to CDC through a secure access management system (SAMS). None of the data sent to CDC contain any personally identifiable information. All project data are 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 treatments (see Attachments 3A–3D). These clinical data elements were developed collaboratively and agreed upon by members of SURRG from all 8 participating jurisdictions. The data elements are a subset of data elements that participating health centers routinely collect as part of

clinical care. CDC staff 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 conduct antibiotic susceptibility testing of *Neisseria gonorrhoeae* culture specimens. Data managers from the local public health laboratory abstract and electronically send antibiotic susceptibility data to the local SURRG data manager.

Field investigation gonorrhea data:

Persons with gonorrhea with reduced antibiotic susceptibility or a gonococcal infection of other public health importance are identified through local laboratory testing and interviewed by health department staff (either by telephone or in-person) who have undergone specialized training to conduct STD field investigations and partner services. Interviewers collect information on demographics, STD clinical history, healthcare-seeking behaviors, behavioral risk factors associated with STDs, and recent partners (see Attachment 3D). The entire interview is expected to last for ~20 minutes. These data elements were developed collaboratively by SURRG participating jurisdictions and CDC. Interview data are maintained in electronic format by the collaborating jurisdictions. Every other month, the local SURRG data manager abstracts, cleans, de-identifies, recodes, and sends data to CDC through a secure access management system (SAMS). At CDC, data are downloaded from SAMS, stored, and maintained by a data manager in

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

Data on race and ethnicity are 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 are 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:

Local health department staff conducting field investigations have all received specialized training in contacting and interviewing persons diagnosed with STDs. These

highly-trained STD field investigators from participating jurisdictions contact patients and partners 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 partners vary by site, but at least three attempts to contact a person are made in all sites. Persons participating in the interview are not be offered reimbursement for their participation, and are 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 collects 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 oversite 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:

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Local data management and analysis are 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) Marion County Public Health Department, and Indiana State Department of Health
4) Guilford County Department of Health and Human Services, and North Carolina Division of Public Health
5) New York City Department of Health & Mental Hygiene
6) Allegheny County Health Department, and Pennsylvania Department of Health
7) Public Health – Seattle and King County, and Washington State Department of Health
8) Milwaukee Health Department, and Wisconsin Division of Public Health