

Strengthening United States Response to Resistant Gonorrhea (SURRG)

OMB 0920-new

Supporting Statement - Part A

July 12, 2018

**Karen Schlanger, PhD
Project lead**

**Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of STD Prevention
Epidemiology and Statistics Branch
1600 Clifton Rd NE, Mailstop E-02
Atlanta, GA 30329**

Voice: (404) 718-5660

Fax: (404) 639-8608

Email: khs4@cdc.gov

Table of Contents

A.

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

EXHIBITS

Table A.12-1	Estimated Annualized Burden Hours
Table A.12-2	Estimated Annualized Burden Costs
Table A.14	Estimated Cost to the Government
Table A.16	Project Time Schedule

LIST OF ATTACHMENTS

Attachment 1.	Authorizing Legislation
Attachment 2.	60 Day Federal Register Notice Publication
Attachment 2a	Public Comments
Attachment 3A.	STD Clinic Facility Data Elements
Attachment 3B.	Non-STD Clinic Facility Data Elements
Attachment 3C-1.	Laboratory Data Elements
Attachment 3C-2	Laboratory Testing Data Elements
Attachment 3D.	Investigation Data Elements

- Attachment 4. List of Collaborators
- Attachment 5. Determination of non-human subjects research
- Attachment 6. Privacy Impact Assessment (PIA)
- Attachment 7. Protocol

A. Justification

- Goal of the study: Strengthening United States Response to Resistant Gonorrhea (SURRG) will enhance US state and local public health surveillance and program infrastructure, build capacity to support rapid detection and public health response to antibiotic-resistant gonorrhea (an urgent public health threat), and advance the understanding of epidemiological factors contributing to antibiotic-resistant gonorrhea.
- Intended use of the resulting data: To guide national recommendations on public health responses to antibiotic-resistant gonorrhea.
- Methods to be used to collect: Data and specimens will be collected at participating sexually transmitted disease (STD) specialty clinics and other partnering clinics, and during outbreak investigations.
- The populations to be studied: Persons with gonorrhea attending one of the participating STD clinics or other participating clinics in the United States, and those within the social and sexual network of persons with gonorrhea, such as sexual partners.
- How data will be analyzed: Trend analyses to identify changes in the burden of antibiotic resistance and cross-sectional analyses to identify risk factors for resistance will be conducted. Network analyses to investigate how drug-resistant gonorrhea spreads will be conducted to investigate to inform public health interventions.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of STD Prevention (DSTDP) requests 3-year approval for a new data collection entitled, *Strengthening United States Response to Resistant Gonorrhea*, as part of a sentinel surveillance and public health program response system. This system is funded by CDC and will be conducted at nine jurisdictions (state and local health departments) in the United States. This data collection and related programs are authorized by the Public Health Service Act, Sec. 301 and 318 (42 USC 241 and 247c) (**Attachment 1**).

CDC estimates that approximately 800,000 persons are infected with gonorrhea annually in the United States.¹ Without antibiotic treatment, gonorrhea can result in pelvic inflammatory disease, infertility, and ectopic pregnancy, and can also facilitate HIV transmission. Gonorrhea control in the United States relies on prompt and effective antibiotic therapy. However, treatment has been complicated by the remarkable and consistent ability of *Neisseria gonorrhoeae* (the bacterium that causes gonorrhea) to develop antibiotic resistance.² In 2013, CDC designated *N. gonorrhoeae* one of three “urgent” antibiotic resistance treats to the United States.³ As part of the federal government’s broad and multipronged Combating Antibiotic Resistant Bacteria (CARB) Action Plan⁴, CDC is implementing Strengthening United States Response to Resistant Gonorrhea (SURRG) to address the threat of antibiotic-resistant gonorrhea. The goals of SURRG are to strengthen the timeliness of surveillance systems, work with state and local health departments to enhance their capacity to monitor and test for antibiotic-resistant gonorrhea, and develop rapid response activities to effectively contain the spread of detected cases of antibiotic-resistant gonorrhea. SURRG directly supports the National Target of maintaining the prevalence of ceftriaxone-resistant *N. gonorrhoeae* below 2%.⁴

As an overview of SURRG, 9 funded jurisdictions will participate. Within these jurisdictions, healthcare providers at ~27 participating clinics (9 sexually transmitted disease [STD] clinics affiliated with a single public health department and 18 other participating non-STD clinic sites) will collect specimens for *N. gonorrhoeae* culture testing from men and women seeking care for possible gonorrhea. Specimens that demonstrate bacterial growth of *N. gonorrhoeae* (called “isolates”) will undergo antibiotic susceptibility testing within several days at the local public health laboratory (using Etest, a ‘ready-to-use’ strip with predefined gradient of antibiotic). Antibiotic susceptibility testing detects antibiotic resistance. Currently, *N. gonorrhoeae* culture specimens (isolates) are needed to conduct antibiotic susceptibility testing to detect resistance. However, because of the widespread availability of molecular tests for gonorrhea, few clinical sites routinely perform culture for gonorrhea (apart from enhanced surveillance programs such as SURRG). Antibiotic susceptibility testing results that demonstrate resistance will be rapidly communicated from local laboratory staff to a designated local health department staff member, who will initiate a local outbreak investigation. The person from whom the resistant isolate was collected will be interviewed by local health department staff to ascertain additional

epidemiological data and information about recent sexual contacts, and will be re-tested at a local healthcare setting to ensure that the patient was cured of the infection. Recent contacts will be interviewed and tested for gonorrhea by local health department.

The participating health departments will collect and transmit to CDC demographic and clinical data about persons tested for and/or diagnosed with gonorrhea in the participating clinics and results of local *N. gonorrhoeae* culture, nucleic acid amplification tests that detect *N. gonorrhoeae*, and antibiotic susceptibility testing of bacterial isolates. Isolates will be shipped each month to one of four Antibiotic Resistance Regional Laboratory Network (ARLN) laboratories for confirmatory antibiotic susceptibility testing (using a technique called agar dilution). The demographic data does not include any personal identifiers, such as full name, medical record numbers etc.

2. Purpose of Use of the Information Collection

The purpose of SURRG is to improve national capacity to detect, monitor, and respond to emerging antibiotic-resistant gonorrhea. The goals of this activity are to inform a more comprehensive understanding of trends and determinants of drug-resistant gonorrhea, monitor for the emergence of resistance, provide a robust evidence base for directing public health action, and evaluate the effectiveness of this approach. CDC currently operates the Gonococcal Isolate Surveillance Project (GISP), which monitors long-term trends in antimicrobial resistance in *N. gonorrhoeae* strains in the United States in order to establish a scientific basis for the selection of gonococcal therapies and to allow pro-active changes to treatment guidelines before widespread resistance and failures of treatment occur. However, the data that GISP provides are not timely enough to allow rapid local programmatic public health responses to an outbreak of resistant infections. A rapid response, involving rapid detection of a resistant infection, rapid (within several days of detection of resistance) interviewing of cases, and rapid interviewing and testing of sexual contacts, is critical for containing the spread of a resistant infection. Data on the effectiveness of rapid response activities are important for identifying effective public health interventions. Patients will also be asked to provide information on their social contacts (acquaintances) that may be interested in obtaining STD testing. This is routinely done for syphilis (because acquaintances are often with the patient's sexual network) and this project is trying to determine if this approach can be beneficial in identifying new cases of gonorrhea in an efficient and targeted manner.

These public health activities will be conducted in the following state and local health departments (SURRG involves partnering of state and local health departments as a single grantee): (1) California Department of Public Health and San Francisco Department of Public Health, (2) Washington Department of Public Health and Seattle-King County Public Health, (3) New York City Department of Health and Mental Hygiene, (4) Hawaii Department of Health, (5) Colorado Department of Public Health and Environment and Denver Public Health, (6) Wisconsin Department of Health Services and Milwaukee Health Department, (7) Indiana State Department of Health and Marion County Public Health Department, (8) North Carolina

Department of Health and Human Services and Guilford County Health Department, and (9) Georgia Department of Public Health and Fulton County Health Department. These sites competed for this cooperative agreement and were selected for funding as a result of a review process conducted in June 2016.⁵

Proposed Data Collection

The proposed data collection is necessary for effectively implementing the activity. Data obtained through these methods has significant utility to the US government, state and local public health departments participating in the project, and other STD prevention partners and stakeholders. These data cannot be obtained in other ways. The data will provide insights into optimal approaches to preventing and controlling antibiotic-resistant gonorrhea and will directly inform CDC recommendations, programmatic public health approaches, and resource allocation.

The project will utilize three distinct but complementary strategies to collect the required information.

Facility-based data

The first strategy will involve local collection of facility-based data. The local health department data manager will abstract clinical data elements routinely collected as part of clinical care and for patients tested for gonorrhea at participating clinics. Data will be de-identified and recoded and transmitted to CDC through secure file transport mechanisms every two months. The data elements to be electronically transmitted to CDC (for a three-year period beginning on the date of OMB approval) are listed in **Attachments 3A and 3B**.

Funded jurisdictions are expected to maintain rigorous procedures to assure the quality and validity of data before submitting to CDC. They will also complete data verification, recode and appropriately structure the data to facilitate merging into the national SURRG datasets. In collaboration with data managers in each jurisdiction, CDC will prepare syntax for data validation that will provide for appropriate quality assurance. Jurisdictions will apply these validation checks and fix the offending records prior to transmission. Locally prepared SAS datasets used for validation and transmission to CDC will not include patients' names, date of birth, phone number, mailing address or medical record numbers. SURRG records from STD clinics will be assigned (by the local or state health department) a unique patient identifier (patient ID) and a unique event identification number for each visit. CDC will only receive the unique identifier and will not have the ability to back-convert the Patient ID to a medical record number. Sites will send data through the secure data network (SAMS), or equivalent, using specified encryption methods on a monthly basis (alternating between the population and facility data files). CDC agrees to accept and securely store these data, accessible only to enhanced SURRG project staff. SURRG data will not be integrated into other datasets maintained by CDC and will at all times be stored on secure servers with fully restricted access.

Laboratory-based data

The second strategy employs local performance of antibiotic-susceptibility testing of *N. gonorrhoeae* isolates and the transmission of testing results from local laboratory staff to the local health department and relevant clinical site. Microbiologists at participating public health laboratories will conduct antibiotic susceptibility testing on *N. gonorrhoeae* isolates collected as part of routine clinical care at the participating clinical sites (see **Attachment 3C-2**). In addition to routine laboratory-based reporting, data managers at each public health laboratory will abstract laboratory results on patients included in the facility-based data collection and will transmit those data to the site data manager through secure file transfer mechanisms (see **Attachment 3C-1**).

Sites are encouraged to provide adequate training to investigators conducting contact with patient laboratory results and to address local human subject's requirements. Locally prepared SAS datasets used for validation and transmission to CDC will not include patients' names, date of birth, phone number, mailing address or medical record numbers. Specimens will be assigned a unique specimen identifier (specimen ID) by the corresponding state/local health department. This specimen ID code will not contain elements of PII, such as parts of a name, social security number, date of birth, or medical record number. CDC will only receive the assigned unique identifier and will not have the ability to back-convert the specimen ID to a medical record number. Sites will send data through the secure data network (SAMS), or equivalent, using specified encryption methods on bimonthly basis. CDC agrees to accept and securely store these data, accessible only to enhanced SURRG project staff. SURRG data will not be integrated into other datasets maintained by CDC and will at all times be stored on secure servers with fully restricted access.

Field-Investigation Data

The third strategy will involve local collection of field investigation-based gonorrhea data. Persons found to be infected with antibiotic-resistant gonococcal infections or other gonorrhea infections of public health significance will be interviewed by local health department staff (using a standardized interview) as part of a field investigation to ascertain epidemiological data and to identify recent contacts, and will be tested locally for gonorrhea to ensure that he or she was cured. Consistent with a public health cluster investigation approach, recent contacts of the patient who may have been exposed to gonorrhea will be interviewed (using a standardized interview, including ascertainment of recent contacts) by specially-trained local health department staff and tested for gonorrhea locally. The estimated sample size will be 360 completed interviews per year.

The primary outcome is information addressing epidemiological questions relevant to detection and responding to the threat of antibiotic-resistant gonorrhea. Sites are encouraged to develop locally-focused protocol documents and/or data collection instruments, provide adequate and

comprehensive training to local investigators conducting patient contact, and to address local human subject’s requirements. Sites are also required to address local human subject’s requirements before data collection begins. Where not otherwise formally required, brief verbal informed consent is obtained from patients prior to eliciting information. Data will be de-identified and transmitted to CDC. Data elements are listed in **Attachment 3D**.

SURRG records from interviews will be assigned (by the local or state health department) a unique patient identifier (patient ID) and a unique event identification number for each investigation. CDC will only receive the unique identifier and will not have the ability to back-convert the Patient ID or other event ID to a medical record number, name, social security number, or date of birth. Sites will send data through the secure data network (SAMS) or equivalent, using specified encryption methods on a bimonthly basis. CDC agrees to accept and securely store these data, accessible only to enhanced SURRG project staff. SURRG data will not be integrated into other datasets maintained by CDC and will at all times be stored on secure servers with fully restricted access

The proposed data collection with frequency of administration of the strategies will include:

Activity	Attachment number
Facility-based data collection	
Electronic transmission of clinical variables routinely collected as standard of care by facilities or clinical networks of providers (STD clinics) and housed within the clinic’s medical record system. Electronic transmissions by the site data manager will occur once every two months. This activity will occur for three years in clinics participating in SURRG.	3A
Electronic transmission of clinical variables routinely collected as standard of care by facilities or clinical networks of providers (partnering non-STD clinic sites) and housed within the clinic’s medical record system. Electronic transmissions by the site data manager will occur once every two months. This activity will occur for three years in clinics participating in SURRG.	3B
Laboratory-based data collection	
Antibiotic susceptibility testing (by Etest) to detect resistance performed by public health laboratory microbiologists at each of the nine jurisdictions. Each test takes ~10 minutes and each jurisdiction will conduct ~700 tests annually.	3C-2
Public health laboratory data managers will transmit testing results and additional associated data to the site data manager for merging with facility-based data	3C-1
Field investigation-based data collection	
Interviews to obtain behavioral and demographic information with	3D

gonorrhoea patients and their recent contacts. This activity will occur for three years in state/local health departments participating in SURRG. Electronic transmission of data to CDC will occur once every 2 months.	
--	--

For all data collections, funded jurisdictions are required to institute rigorous procedures to assure the quality and validity of data before submitting to CDC. In collaboration with data managers in each jurisdiction, CDC will prepare protocols for data validation that will provide for appropriate quality assurance. No SURRG data received at CDC will ever include patient names, social security numbers, email addresses, home addresses, zip code, telephone numbers, or medical record numbers. All records will be assigned a unique event identification number (for each visit) as well as a unique patient identification number by the corresponding state/local health department. CDC will only receive these de-identified codes and will not have the ability to link IDs to medical record numbers or any other patient identifying information. Sites will send data through CDC's Secure Access Management System (SAMS) using RSA-standard encryption methods. CDC will accept and securely store these data, accessible only to the SURRG project staff. SURRG data will at all times be stored on secure servers with fully restricted access.

3. Use of Improved Information Technology and Burden Reduction

CDC will provide sites with standardized SAS data structures with variable names, lengths and types defined for all requested datasets. Data will be abstracted by local sites from pre-existing electronic medical records in collaborating clinical facilities. Funded jurisdictions will complete data verification and validity checks on datasets prior to transmission to CDC. In collaboration with data managers in each jurisdiction, CDC will require protocols for data validation that will provide for appropriate quality assurance. Jurisdictions will assure validity of the data prior to transmission. Data will be uploaded every two months by trained data managers at collaborating sites. Record-level data will be transmitted to CDC through SAMS every 2 months. Automation of processes wherever possible will be required at the local level to significantly lessen the burden on collaborating health department staff.

De-identified data will be received, 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. Datasets received at CDC will be validated and appended to the national SURRG database within two weeks of receipt. Completeness of reporting and the quality of data will be monitored by CDC for every data transmission. Site visits, regular communications with collaborating health departments, and data quality checks will provide opportunities for evaluation and troubleshooting of these processes.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is the only agency that conducts national STD surveillance through the funded assistance of state and local health departments. Monitoring of *Neisseria gonorrhoeae* antibiotic susceptibility is conducted by CDC's Gonococcal Isolate Surveillance Project (GISP) (OMB number 0920-0307 exp. 02/28/2019). GISP is a CDC-supported sentinel surveillance system that solely monitors long-term trends in resistance and informs treatment guidelines. Resistance testing is performed by a regional laboratory network and results are available 1-3 months following specimen collection. However, rapid public health action and field investigations to halt or slow the spread of identified resistance must occur within days-weeks to be effective. SURRG addresses this gap by supporting the establishment of local capacity to conduct rapid resistance testing, which will facilitate rapid public health action. SURRG will also provide critical multi-site information on the effectiveness of rapid public health responses to antibiotic-resistant gonorrhea that is not available elsewhere. GISP only includes the bacterial isolates from the first 25 men presenting to participating STD clinics with gonococcal urethritis each month. This population provides a stable population for long-term surveillance of resistance trends. In contrast, SURRG will include all gonococcal isolates collected by participating STD clinics each month, regardless of the gender of the patient or anatomic site of the infection. SURRG will also include non-STD clinic healthcare settings, so as to expand the reach of local detection of resistance.

Efforts have been made to prevent duplication of effort, including conducting extensive, systematic searches of electronic databases of published articles and abstracts, attending local, national, and international conferences relevant to the topic, communication with non-federal colleagues at state and local health departments as well as colleagues within the government. Apart from the proposed project, this type of public health activity and data collection are not currently being conducted specific to antibiotic-resistant gonorrhea because jurisdictions lack the capacity and resources to perform these activities.

It is possible that some bacterial isolates from men with urethritis who attended participating STD clinics will be included in both GISP and SURRG. Results from laboratory testing (by agar dilution technique) of the isolate by a regional lab network will be used in GISP long-term surveillance trends. In SURRG, the isolate will undergo local rapid resistance testing (by Etest technique) and results used for local public health action. Data collection has been carefully harmonized between the 2 projects to reduce the burden on the local jurisdictions as much as possible. Importantly, input from the participating jurisdictions on how to minimize the burden on them has been repeatedly sought (through phone calls, in-person discussions, webinars, and by email) and rigorously and extensively incorporated into the processes.

5. Impact on Small Business or Other Small Entities

Respondents include city, county, and state health departments and public health laboratories. Data/information collection instruments have been held to the absolute minimum of questions

required for intended use of the data/information and respondents are permitted to report data electronically to reduce burden and improve data quality.

Respondents applied to participate in SURRG and participate voluntarily.

6. Consequences of Collecting the Information Less Frequently

Past experience indicates that gonococcal resistance patterns can change rapidly. SURRG data will be reported to CDC every 2 months. Earlier detection of trends and emergent issues will support timelier implementation of prevention and control effort, resulting in prevention and control of additional gonorrhea transmission. If these data are not available, CDC, state, and local health departments will not have the necessary information to make evidence-based decisions regarding gonorrhea prevention program planning and resource allocation. In addition, CDC, state, and local health departments will not be able to support implementation of the National Strategy for Combating Antibiotic Resistant Bacteria and achieve the National Target of maintaining ceftriaxone-resistant gonorrhea at <2% through 2020.⁴

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register notice was published in the Federal Register on November 15, 2017 [Vol. 82, No. 220, pages 53501-53503] (**Attachment 2**). CDC received one non-substantive comment on this 60 day public notice indicating that the SURGG related diseases that CDC is proposing to address with this collection is attributed to the open borders of America and that in order to clean up the diseases and stop wasting federal dollars, the borders should be closed. The commenter stated that CDC should stop the research (**see Attachment 2a**). In addition the commenter did not provide any contact information. Therefore, a CDC response was not sent.

CDC has discussed the proposed SURRG methodology to external stakeholders and experts for comment, including the STD subcommittee to the Association of Public Health Laboratories (APHL) and the STI section of Public Health England (PHE). Their responses were extremely positive.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection activity.

Each state has laws requiring certain diseases, including gonorrhea and syphilis, be reported at the local/state level. STD programs in local/state health departments routinely prioritize case investigations on persons with these notifiable STD conditions. This type of required reporting uses personal identifiers and enables the states to identify cases where immediate disease control and prevention is needed. The local/state health departments also collect personal identifiers about recent contacts, to conduct disease control activities. The personally identifiable information (PII) that is collected at the local level, through their routine activities, includes the patient's name, contact information (including street address and phone number), gender, race/ethnicity, and date of birth to facilitate disease control investigations. The health departments' collection of PII is used for 3 purposes: (1) ensuring the proper identification and follow-up of cases, (2) ensuring that infected persons receive appropriate treatment and sexual contacts who need treatment are traced, and (3) investigate and control outbreaks.

This data collection (SURRG) provides enhanced behavioral, demographic, and clinical information on gonorrhea cases reported to state and local health departments, allowing a better understanding of the epidemiology of STDs and drug-resistant gonorrhea and to inform national and local gonorrhea prevention efforts. These PII are maintained independent of data collected through the course of SURRG interviews. None of the patient identifiers such as patient names, medical record numbers, home address or zip codes, or birthdates are included in records forwarded to CDC as a requirement of this project. Census tract information are used in the aggregate to identify health disparities in treatment, clinical outcomes and access to care based on distance from resident census tract to provider location. Information on gender, age, race/ethnicity, and gender of sex partner are collected (**Attachments 3A-D**) and transmitted to CDC because STDs disproportionately impact racial/ethnic and other (including sexual) minorities.

In the data sent to CDC, respondents are identified by a unique patient ID code. The non-name-based unique patient ID, assigned by either the state or local health department or the sentinel facility, is created solely for the purposes of surveillance and is not itself a medical record number or social security number. The unique patient ID code for the STD clinic patients are assigned and maintained by the participating facility. Neither the health departments nor CDC can use this number in the identification of individual patients seeking care in these facilities. In the field-investigation component of SURRG, the unique person ID code is assigned by the local grantee to each gonorrhea case using data on case reports submitted by providers/ laboratories pursuant to local reporting regulations. These records can only be re-identified at the local level. Data is encrypted and transmitted via CDC's Secure Access Management System (SAMS). At CDC, enhanced SURRG data are maintained on secure servers behind the CDC firewall. Password-protected access is required and directory-specific user access rights are assigned by

a CDC data steward. Restricted access to STD data is provided to DSTDP/CDC scientists, researchers, and program managers. CDC will work with collaborating sites to design a plan to destroy site-specific SURRG data files after data analyses is completed.

For clinical and demographic variables from the participating facilities, written informed consent was not required at any of the facilities for the collection of de-identified electronic clinical data elements maintained in archived databases at the clinics. This is deemed to be of minimal risk and the data collection could not be conducted with written informed consent. The data transmittals do not have any personal identifiers (patient names, initials, date of birth, contact information, or medical record numbers). Patients are identified in the database only by a unique patient ID code and CDC does not receive any information that could be used to personally identify any data records.

For the field-investigation-based activity, state and/or local health departments 1) contact the individuals diagnosed with gonorrhea, under local public health authority to conduct disease investigations, and 2) contact their partners and those within their network as part of routine STD control activities. CDC does not conduct any interviews with patients or partners. The interviews are conducted by trained local health department staff in a private location where the questions and responses cannot be overheard by others. The health department staff conducting these investigations (disease investigation specialists [DIS]) are required to undergo specific DIS training that includes education about patient and data confidentiality. Individuals being contacted for interviews are verbally consented over the phone or in-person prior to the administration of the questionnaire. Participants are told they may decline to participate without penalty or if they agree to participate, they may refuse to answer any of the survey questions. They are informed that the data will be used to improve gonorrhea prevention services for persons at increased risk of STDs and gonorrhea in their area, and that aggregated data may be released in published reports.

Data Transmittals and Safeguards

Data transmission from sites to CDC will be restricted to CDC's Secure Access Management Services (SAMS). SAMS is an approved federal information technology system that provides authorized, validated users secure, encrypted access to CDC file transfer applications. The encrypted data will be stored in a secure CDC server with strictly controlled and restricted access rights.

The Division of STD Prevention, Surveillance and Data Management Branch is charged with the responsibility of maintaining the privacy, security, and scientific integrity of all SURRG databases. The Data Manager will be designated as custodian of the SURRG data files and will be responsible for assuring all conditions of use and for security arrangements to prevent unauthorized use of, or access to SURRG data. Access to the data shall be limited to specific SURRG staff members of the Division of STD Prevention and designated collaborators of the study in the performance of their assigned duties. The SURRG Project Officer(s) will be

responsible for granting access to SURRG data to other CDC staff in the Division of STD Prevention as needed. The SURRG collaborating sites will be promptly notified of any CDC personnel changes that affect access to the data for this project. All CDC personnel with data access have completed, and will remain current with the annual Health and Human Services Information Security Awareness Training. A record of the completion of security training for all CDC staff is maintained by the CDC Information Technology Services Office (ITSO). State and local surveillance program personnel agree to abide by the Data Security and Confidentiality Guidelines for NCHHSTP. These guidelines can be accessed at the following link: (<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>) and will be required to document compliance as part of annual project reporting.

Local collaborators retain full control of and rights to analysis, research, and publication of their locally collected data, regardless of whether these data are also provided to CDC as part of SURRG activities.

CDC may retain SURRG data for appropriate analytic purposes as long as the data are protected as described herein. CDC will annually review the need for the data and shall destroy all copies of the data if it is determined that no further analysis will be conducted.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The approved Project Determination of Form (Attachment 5) indicates that because the project is a routine disease surveillance activity, the protocol is exempt from review by CDC's IRB.

Justification for Sensitive Questions

The collection of information about STDs itself is sensitive because of stigma associated with STD/HIV infection. In addition, the modes of transmission of STDs (through sexual contact) and contributing risk factors necessitate the collection of sensitive data, including sexual practices, drug use, and HIV status. In keeping with the purpose of this data collection, other sensitive data are collected about specific behaviors, experiences or conditions that have been shown to be associated with STD infection (**Attachments 3A, 3B, and 3D**). Although the information requested from STD clinic patients and interviewed participants is highly sensitive, the purposes of SURRG cannot be accomplished without their collection. Collected data are used to understand barriers to engaging in protective behaviors and to using STD prevention services. These data are also used to enhance STD prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit STD/HIV, and control the spread of resistant gonorrhea.

The information will be used only in the aggregate and only for the purposes of this project and will be kept private to the extent allowable by law.

Insurance status is an important question to include. Access to quality STD prevention and treatment is key to reducing STDs in the United States. Timely screening or medical examination and prompt antimicrobial treatment of gonorrhea are critical to prevent complications of gonorrhea for individual patients and for public health gonorrhea control; prompt detection and treatment reduces the likelihood that gonorrhea will be further transmitted to partners and others in the community. Lack of health insurance poses barriers to access to timely and high-quality healthcare. Understanding whether persons with gonorrhea or those at high risk for gonorrhea have health insurance is critical for informing cost-effective prevention efforts by local and state health departments (for example, whether to work with private providers or whether health department-driven screening events are needed) and for developing effective gonorrhea prevention and control efforts that leverage the strengths of both the public health and healthcare infrastructure.

Knowledge of the type of insurance is important because healthcare access may differ across different types of insurance categories and the likelihood of having received adequate STD care can differ across insurance type. For example, chlamydia screening rates differ by insurance type. Data on whether persons with gonorrhea or those at risk for gonorrhea have healthcare insurance is also very useful locally: many health department STD clinics are investigating third-party billing of clients with insurance. Participants will be asked whether they have insurance and whether the insurance is public or private. No portion of a social security number, medical identifier, or insurance policy number will be collected or transmitted.

The STD Surveillance Network (SSuN) (0920-1072; expiration 6/30/2018) collected data on social determinants of health (SDH) and gonorrhea, but does not include data on gonorrhea resistance. Furthermore, while several national surveys (NHIS, NHANES, NSFG) collect data on health insurance (and the proposed question in this ICR was modeled after the previously OMB-approved formats used in these data collection instruments), these surveys sample the general

US population and provide no information related to the insurance status of populations with or at high risk for gonorrhea or resistant gonorrhea. As more gonorrhea control take place outside of the traditional STD clinic setting, a more clear understanding of health care access issues (including health insurance) will be needed to inform prevention and control approaches. Our use of previously used question formats also allows us to compare results in persons with resistant gonorrhea to results among the general population or those with sexual risk from surveys such as the National Survey of Family Growth (NSFG) and National Health and Nutrition Examination (NHANES).

Census tract, city, county, state information is collected for the purposes of spatial analysis of the data to understand the geographic distribution of disease and risk and to understand the spread of resistant gonorrhea.

The context in which interview questions are asked help to overcome their potential sensitivity. There are several steps taken SURRG to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Most questions allow for responses of “don’t know” or “refuse to answer.”
- The interview questions are carefully organized to lead smoothly from one topic to another.
- Transitions are clear to respondents and the need for the information explained.
- Assurance about the privacy of the information are reiterated.

All interviews are conducted by trained local/state health department staff in a private location during established operating hours. No interviews are conducted without the verbal consent of the respondent.

12. Estimated Annualized Burden Hours and Costs The respondents for Strengthening United States Response to Resistant Gonorrhea (SURRG) include (1) data managers at the 9 funded SURRG sites, (2) clinic data managers at the non-STD clinic health centers participating in SURRG, (3) public health laboratory microbiologists, (4) public health laboratory data managers, and (5) persons diagnosed at a participating SURRG site with gonorrhea of public health importance, such as a drug-resistant infection, and those in their social and sexual network.

(1) SURRG data managers:

Every two months, data managers from each of the 9 funded jurisdictions will:

- a) Abstract line-listed clinic visit data from participating STD clinics for all patient visits that included testing for gonorrhea that occurred in the previous two months.
- b) Receive line-listed clinic visit data from participating non-STD clinic healthcare sites for all patient visits that included testing for gonorrhea that occurred in the previous two months.
- c) Receive laboratory results (e.g. antibiotic susceptibility testing) from public health laboratory data managers
- d) Merge clinic visit data with public health laboratory results
- e) Abstract line-listed data for any person for whom a SURRG interview was attempted and/or completed in the previous two months
- f) Clean, recode, and structure data in accordance with SURRG program guidance
- g) Complete data verification and validity checks (per CDC SURRG program guidance) on dataset prior to transmission to CDC, and
- h) Transmit all data files to CDC through secure file transport mechanisms (SAMS)

Within two months of the end of each project year, the SURRG assigned data manager in each jurisdiction will also compile, clean, validate, and transmit an annual cumulative project dataset to CDC through secure file transport mechanisms (SAMS) (for a total of 7 data transmissions per year). This final validated annual dataset from each jurisdiction will be archived and become the primary repository for that site's annual reporting. Nine (9) respondents, providing 7 data transmissions per year with an average of 16 burden hours yields 1008 burden hours for the local data managers (**Attachment 3A**).

Clinic data managers at non-STD clinic health centers:

A total of 18 non-STD clinic health centers will be participating in SURRG (e.g. HIV clinics, reproductive health centers, and emergency rooms). Every two months, data managers from each of these locations will abstract and clean all required data on all patients tested for gonorrhea. Data managers will transmit the data by secure file transport mechanism to the local SURRG data manager. We have estimated that it will take data managers at each non-STD SURRG location approximately 3 hours each time they abstract, clean, and transmit SURRG data. 18 Data manager at non-STD clinic health centers, provide 6 responses each with 3 hours per response, yields 324 annual burden hours (**Attachment 3B**).

Laboratory-based data:

Public health laboratories from each of the 9 SURRG funded jurisdictions will conduct antibiotic susceptibility testing via Etest on all *N. gonorrhoeae* cultures from all 10 STD clinic sites and 18 non-STD clinic sites participating in SURRG. Each Etest takes approximately 10 minutes (10/60) of staff time, and an Etest of control strains will also be conducted approximately twice per week at each laboratory. On average, each jurisdiction will conduct approximately 600 Etests per year for patient care, plus 100 Etests per year on control strains for quality assurance. Thus a total of approximately 700 Etests per year per grantee will be performed.

Nine (9) public health laboratory biologists, provide 700 laboratory testing data responses each taking 10 minutes per response, yields 1,050 annual burden hours (**Attachment 3C-2; Part II PRA Worksheet Att 3C-2**).

In addition to routine laboratory result reporting, a laboratory data manager will abstract laboratory data for persons included in the SURRG clinic-based data collections and associated data (such as submitting site and timing of result reporting) and will transmit those data to the local SURRG data manager through secure file transport mechanisms. We estimate that the 9 laboratory data managers at each local public health lab will spend approximately 1 hour each time they abstract, clean, and perform 6 project data transmissions for a total of 54 annual burden hours (**Attachment 3C-1; Part II PRA Worksheet Att 3C-1**).

Persons diagnosed with gonorrhea and those in their social and sexual network:

Health department staff will interview any person diagnosed (via Etest) with antibiotic-resistant gonorrhea or a case of gonorrhea of public health significance index case), his/her social and sexual contacts, and the sexual contacts of the index case's sexual contacts. On average, each jurisdiction will identify four drug-resistant isolates each month. These isolates which will spur field investigations, which will result in six additional interviews each month. An estimated total of 120 interviews will occur annually at each site, for a total across the 9 sites of 1080 interviews each year. Each interview will take ~30 minutes. This activity produces 540 annual burden hours (**Attachment 3D**).

The Antibiotic Resistance Laboratory Network (ARLN) serves as a referral source for susceptibility testing of multiple bacterial and fungal pathogens of public health importance and is not included in the SURRG burden calculations.

The burden table below reflects the total estimated annualized respondent burden hours for the project.

A12a. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Local SURRG data manager*	Facility Data Elements Attachments 3A	9	7	16	1008
Data manager at non-STD clinic health centers	Non-STD clinic Data Elements Attachment 3B	18	6	3	324

Public Health Laboratory Microbiologist**	Laboratory Testing Data Elements Attachment 3C-2	9	700	10/60	1,050
Public Health Laboratory Data Manager**	Laboratory Data Elements Attachment 3C-1	9	6	1	54
Gonorrhea Patients, Social and Sexual Contacts	Field Investigation Data Elements Attachment 3D	1080	1	30/60	540
Total					2976

* The SURRG data manager is responsible for abstracting data from the 9 participating STD clinics.

** Burden calculations for Public Health Laboratory Microbiologist shown in Part II PRA Worksheet Att 3C-2; burden calculations for Public Health Laboratory Data Manager shown in Part II PRA Worksheet Att 3C-1

The annualized burden cost is estimated in table A12b below.

Hourly wages for each of the four respondent categories were determined as follows:

- The mean hourly wage for non-STD clinic, laboratory, and SURRG database administrators, were all estimated at a rate of \$41.89. Estimates of hourly wage rates are based on the 2016 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for Database Administrators in the United States (accessed at <https://www.bls.gov/oes/current/oes151141.htm>).
- The mean hourly wage for a microbiologist was estimated at a rate of \$36.95 based on the 2016 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for Microbiologists in the United States (accessed on May 22, 2017 at <https://www.bls.gov/oes/current/oes191022.htm>).
- The mean hourly wage for gonorrhea patients and their sexual and social contacts was estimated at a rate of \$23.86, which is the mean hourly wage reported on the 2016 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates across all occupations in the United States (accessed on May 22, 2017 at https://www.bls.gov/oes/current/oes_nat.htm).

Table 12.B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden hours	Hourly Wage Rate	Total Respondent Cost
Local SURRG data manager	1008	\$41.89	\$42,225.12
Data manager at non-STD clinic health centers	324	\$41.89	\$13,572.36
Public Health Laboratory Microbiologist	1050	\$36.95	\$38,979.50
Public Health Laboratory Data Manager	54	\$41.89	\$2,262.06
Gonorrhea Patients, Social and Sexual Contacts	540	\$23.86	\$12,884.40
Total	2976		\$109,923.44

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Federal Government

The total annualized cost to the government is \$5,654,830. The total cost to the government over the 3-year period is \$16,964,489. Funding to the grantees is being provided through the Epidemiology and Laboratory Capacity for Infectious Diseases Funding Opportunity Announcement. CK14-1401PPHF.⁵ The annual cost is summarized in Table A.14.

Table A.14: Estimated Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Cost (dollars)
Direct Costs to the Federal Government	CDC Data Manager (GS-12, 0.2 FTE)	\$15,141
	CDC Laboratory Personnel (GS-11, 0.6 FTE)	\$37,896.6
	CDC Epidemiologist (GS-13, 1.0 FTE)	\$90,023
	CDC Epidemiologist (GS-12, 1.0 FTE)	\$75,705

Operational	Travel (site visits)	\$ 10,000
Other Expenses	California site cost	972,245
	Colorado site cost	627,235
	Georgia site cost	385,111
	Hawaii site cost	688,498
	Indiana site cost	608,578
	New York City site cost	868,252
	North Carolina site cost	508,496
	Washington site cost	767,649
	Total cost to the Federal Government	\$5,654,830

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We anticipate initiation of data collection to be September 3, 2018. The project will continue through September 2, 2021. Preliminary data analysis is expected to begin 4–6 months after OMB approval. Interim data analyses will be completed 12 months after OMB approval. Additional data analysis will occur at least annually during the time period of the approved 3-year project period. Data analyses include descriptive analyses, trends in gonococcal antimicrobial resistance over time, and network analyses of partnerships. Analyses of the data will be published in scientific and public health journals and presented at scientific meetings.

Table A.16: Project Time Schedule

Activity	Time Schedule
Collection of isolates and clinical/demographic data from participating clinics and jurisdictions	Every other month after OMB approval
Data management and validation of data collected	Quarterly after OMB approval
Dissemination of results via annual report	12 months after OMB approval and annually

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

There are no exceptions to the certification for the clinical sites and GISP regional laboratories. OMB/PRA clearance is not required for the Antibiotic Resistance Laboratory Network (as described previously).

References

1. Satterwhite CL, Torrone E, Meites E, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. *Sex Transm Dis* 2013;40(3):187-93.
2. Unemo M. Current and future antimicrobial treatment of gonorrhea - the rapidly evolving *Neisseria gonorrhoeae* continues to challenge. *BMC Infect Dis* 2015;15:364.
3. CDC. Antibiotic Resistance Threats in the United States, 2013. Available at: <http://www.cdc.gov/drugresistance/threat-report-2013/index.html>.
4. National Strategy for Combating Antibiotic-Resistance Bacteria. https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf. Accessed May 11, 2016.
5. Department of Health and Human Services, Centers for Disease Control and Prevention. Epidemiology and Laboratory Capacity for Infectious Diseases Funding Opportunity Announcement: CK14-1401PPGH, Continuation Application/Interim Progress Report Guidance, FY2016 (August 1, 2016-July 31, 2017).