Epidemiology and Laboratory Capacity (ELC) –Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity 2016

ELC Project K8

Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity

Navigation

Click the name of a section below while holding the control key to jump to specific sections of this document.

Guidance

The following work plan will outline the awardee's plans, milestones, and expected outcomes related to the project described in attachment Antibiotic-Resistant Gonorrhea of the ELC 2016 Application. Please review this guidance prior to completing this application.

If there are any questions or concerns while completing this application, please contact the ELC or Program POC to address and resolve the issue.

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Document ID: ELC-2016-Antibiotic-Resistant Gonorrhea 1 1 1 1 1 1 1 1 1 1

Awardee Jurisdiction

Please select your Awardee jurisdiction.

States: Alabama through Mississippi (Alphabetical)	States: Missouri through West Virginia (Alphabetical)	Wisconsin, Wyoming and Non-State Applicants (By Type)
California	Select One	Select One

Project Approach

Problem Statement

In completing this section, reference the component projects 'Problem Statement' within the funding opportunity guidance and articulate its applicability and special considerations to the applicant jurisdiction. *Please limit the response to this section to half a page - This section is unrestricted to allow entry of additional materials beyond text (including graphics, pictures, etc.) as necessary.*

In 2013, CDC identified antibiotic-resistant *Neisseria gonorrhoeae* (ARG) as an urgent public health threat requiring significant resources to detect and prevent cases in the United States. California (CA) and San Francisco (SF) are areas of particular concern. In 2014, CA had the most gonorrhea (GC) cases of any state. In 2015, there were 54,307 GC cases, and from 2011 to 2015 male cases ages 15-44 increased 113% and female cases ages 15-44 increased 67%. Furthermore, SF has the highest GC case rate in CA; in 2015, 4266 reported cases represented a 30% increase from 2014. In 2013, the SF case rate was 313.2/100,000, which exceeded the case rate for the Los Angeles metropolitan statistical area (MSA), the New York MSA, the state of CA, and the United States (US) as a whole. Prevention and control of GC are key responsibilities of state and local sexually transmitted disease (STD) programs and rely on timely and effective antibiotic treatment. However, GC has repeatedly developed resistance to antimicrobials including sulfonamides, penicillin, tetracyclines, and fluoroquinolones. Data from the CDC Gonococcal Isolate Surveillance Project (GISP) have shown that decreased antibiotic susceptibility to cephalosporins, the current mainstay of GC treatment, is more likely to be detected in specimens from the Western US compared to other US regions, and from men who have sex with men (MSM) compared to men who have sex with women (MSW). With large populations of MSM and high rates of GC, CA and SF are critical jurisdictions to implement effective surveillance and control of ARG.

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Purpose

Describe in 2-3 sentences specifically how the application will address the project's problem as described in the component project's 'Problem Statement.'

Given California's increased epidemiologic risk for ARG, both the San Francisco Department of Public Health (SFDPH) and California Department of Public Health (CDPH) have established efforts to prepare for and respond to this public health threat. Our proposed California-San Francisco Rapid Detection and Response Project (CA-SF GC RDR) will support, expand, and accelerate efforts to combat ARG in San Francisco, by 1) developing and implementing protocols for rapid identification and response to ARG cases, 2) expanding surveillance to additional clinic sites, populations including females and youth, and anatomic sites of infection, and 3) collaborating throughout the surrounding Bay Area region to provide comprehensive rapid response to ARG cases. Rigorous data collection and evaluation of novel methods for GC surveillance, laboratory testing, and case investigation will inform preparedness for rapid ARG detection and response throughout California.

Applicant Capacity

The below table provides some specific questions regarding gonorrhea morbidity and Public Health Lab capacity. Following the table is a free-response section for you to provide more information about your capacity.

Selection of a Local Health Jurisdiction	
If your organization is <u>not</u> a local health department, name the local health jurisdiction with whom you plan to partner to implement programmatic activities:	San Francisco Department of Public Health
Does the jurisdiction currently receive and electronically/automatically processes electronic lab reports (ELR)?	Yes, at state and local levels
Presence of a Categorical STD Clinic (a clinic whose primary mission is to provide diagnosis, treatment, counseling, and sex partner notification for STDs.)	
Provide the name(s) and location(s) of categorical STD clinics that serve the selected jurisdiction. If you will perform activities in only a select number of STD clinics, please denote the selected clinics:	San Francisco City Clinic 356 7th Street San Francisco, CA 94103
Does/do the categorical STD clinic(s) that you proposed to work with utilize electronic medical records (EMR)?	Yes, All
If only some of the categorical STD clinics that you	

propose to work with utilize EMR, please indicate which clinics use EMR and which do not:	
Gonorrhea Morbidity	
How many cases of gonorrhea (GC) were reported in 2015 in the selected local jurisdiction?	Female: 372 Male (Overall): 3829 -- Male (Men who have sex with men): 3067 -- Male (Men who have sex with women only): 140 Non-Hispanic White: 1887 Non-Hispanic Black: 387 Hispanic: 631 Other races: 1352
How many cases of GC were reported in 2015 from the categorical STD clinic(s) where you plan to implement activities? ***Note: This program requires that at least one categorical STD clinic must diagnose at least 200 GC cases per year.***	Number: 790 Proportion of total GC cases reported in the selected jurisdiction diagnosed by the categorical clinic(s): 18.50%
How many cases of GC from the selected local jurisdiction were cultured and tested for antibiotic susceptibility in 2015?	Number: 273 Proportion of total GC cases reported in the selected jurisdiction (i.e., not limited to the categorical clinics above): 6.40%
Laboratory Capacity	
Please provide the name and location of the state/local public health laboratory that will be performing antibiotic susceptibility testing for the project	Name: San Francisco Public Health Laboratory Location: 101 Grove Street, Room 419 San Francisco, CA 94102
Does the selected public health lab currently culture GC specimens for antibiotic susceptibility testing or diagnostic purposes?	Yes
If the selected public health lab currently cultures GC, please provide information on how many specimens the lab cultured and tested for antibiotic susceptibility in 2015 by test type.	Agar dilution: Disc diffusion: E-testing: 73

	Other:
If the selected public health lab currently cultures GC, please provide information on the mean time and range (in days) between specimen collection and the results being returned to the provider.	Mean time (days): 3 Range (high side, in days): 15 Range (low side, in days): 1

Address the jurisdiction's current capacity to successfully implement the proposed strategies and activities (including describing staff and other infrastructure already in place that you will build upon) to meet project period outcomes. *Please limit the response to this section to 1 page - This section is unrestricted to allow entry of additional materials beyond text (including graphics, pictures, etc.) as necessary.*

The SF Department of Public Health (SFDPH) Population Health Division (PHD) is a longtime leader in STD prevention, and contains the premier categorical STD clinic in CA, San Francisco City Clinic (SFCC). SFCC has been a CDC GISP site for 30 years; for the first half of 2015, 203 cases of gonococcal urethritis were diagnosed at SFCC, 126 of which were submitted to the regional GISP laboratory via SFDPH Public Health Laboratory (PHL), itself a state-of-the-art microbiology laboratory with demonstrated excellence in both standard and innovative GC testing, including being among the first to utilize GC NAAT. Sequence analysis of SFCC GC specimens at PHL in 2008 demonstrated the presence of two previously undescribed penA alleles associated with elevated cephalosporin MICs. PHL implemented Etest in 2011 to provide susceptibility data 2-3 weeks before GISP results were available on specimens from four public health clinics across CA (including SFCC). Susceptibility data from PHL and GISP are stored in the SFDPH STD data system (ISCHTR - Integrated Surveillance and Clinical Health Tracking Registry), a robust data management system that enables timely analyses for continuous quality improvement.

The California Department of Public Health (CDPH) STD Control Branch (STDCB) coordinates STD prevention and control across CA and is creating an advanced data management system to track California GISP isolates and any suspected GC treatment failures or ARG cases. STDCB has worked with LHJs to not only respond to GC outbreaks, treatment failures and ARG but also to conduct many successful enhanced GC projects, including Etest and an evaluation of an alternative GC culture medium (InTray GC) with SFDPH, a test of cure study with San Mateo, a collaboration with San Luis Obispo to evaluate a cluster of disseminated gonococcal infections, and partner services for patients with GISP alerts (through which, in 2015, SFDPH interviewed 12 of 14 patients with reduced susceptibility). Additionally, CA and SF collaborated to analyze partner services data from SF and neighboring Bay Area counties, which revealed that 41% of sexual partnerships in a large network of early syphilis cases in the SF-Bay Area region were between persons who resided in different counties, reinforcing the importance of collaborative disease control efforts. In late 2015, STDCB began working

closely with the CDPH Microbial Diseases Laboratory Branch (MDL) to build capacity for GC culture and antimicrobial susceptibility testing (AST). MDL is available to perform whole genome sequencing and provide subject matter expertise on molecular diagnostics. Both CDPH and SFDPH receive funding for the STD Surveillance Network (SSuN) to conduct enhanced population-based GC surveillance.

The *CA-SF GC RDR* leadership team has extensive STD experience. ***Dr. Susan Philip, MD, MPH***, the SFDPH PHD Disease Prevention and Control (DPC) Branch Director, and STD Controller for SF, will serve as the SF Principal Investigator for this project. She has over 13 years of experience in STD and HIV clinical care, epidemiology, research and evaluation. Key units in DPC include SFCC, PHL, and all SFDPH DIS staff. ***Dr. Trang Nguyen, PhD, MPH*** is a senior epidemiologist with extensive knowledge of the STD surveillance and program activities. She will work closely with the *CA-SF GC RDR* staff to meet objectives, assisting them in engaging all key stakeholders and staff to develop and implement the evaluations. ***Dr. Mark W. Pandori, PhD, HCLD(ABB)*** is the interim Director for PHL. He is a national expert in public health laboratory methods for GC and other STDs, and led many of the PHL innovations in GC testing described above. ***Dr. Heidi Bauer, MD, MS, MPH*** is the Chief of the CDPH STDCB and will serve as the CDPH Principal Investigator for this project; she has over 15 years of experience in STD prevention program development, epidemiology, research, and evaluation. ***Dr. Juliet Stoltey, MD, MPH*** is Chief of the Office of Science and Policy and the Public Health Medical Officer of CDPH STDCB; she has expertise in infectious diseases and STDs, 6 years of experience in STD and HIV clinical care, serves as the lead for ARG efforts at STDCB, and will work closely with the *CA-SF GC RDR* staff to meet objectives. ***Dr. Vishnu Chaturvedi, PhD*** is a board-certified laboratory director for MDL and recognized academic scientist, educator, editor and subject matter expert with an eighteen-year track record in managing people and processes that ensure the highest quality public health laboratory operations.

Strategy 1

Strategy: Strengthen local resistant GC threat coordination and epidemiological capacity

Add New Activity

Strategy 1: New Activity #1

Name (500 Character Maximum):

Designate an epidemiologist coordinator responsible for local resistant GC activities

Implementation Plan (1000 Character Maximum):

The San Francisco Department of Public Health (SFDPH) will define a scope of work and hire a GC Epidemiologist Coordinator (EC). This coordinator will be the primary person responsible for the activities of the CA-SF GC RDR in San Francisco. Additionally, CDPH will hire a Regional GC RDR Coordinator (RDRC). Named partners of SF cases come from both inside and outside SF and historically STD outbreaks in CA have involved multiple independent jurisdictions. Thus, a regional effort is necessary for both capacity building and surveillance to facilitate inter-jurisdictional coordination, data-sharing, and partner follow-up to provide a comprehensive public health infrastructure and capacity for detection and response, and to better characterize sexual transmission networks. This position will provide overall epidemiologic support and coordination with SFDPH and other regional and statewide partners.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Hire SFDPH GC Epidemiology Coordinator	Susan Philip and Trang Nguyen	Aug 2016	Nov 2016
2	Hire CDPH Regional GC RDR Coordinator	Heidi Bauer and Julie Stoltey	Aug 2016	Nov 2016
3			Select One	Select One

Strategy 1: New Activity #2

Name (500 Character Maximum):

Develop flow charts and definitions detailing case reporting, laboratory testing, and epidemiologic investigation and analysis

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC will identify protocols, data systems, and staff associated with GC case reporting, laboratory testing, and epidemiologic investigation and analysis to develop a plan to meet project deliverables. The GC EC will work with key staff to develop the timeline for expanded GC culture and AST to include female and extragenital specimens of SFCC patients, and from the 3rd Street Youth Center and Clinic (a high volume youth clinic primarily serving African Americans in the highest adolescent STD prevalence area). The CDPH Regional GC RDRC will work closely with the SFDPH GC EC

to develop updated workflows that: link to regional GC efforts; facilitate data sharing on partners and for regional and state epidemiologic analyses; and ensure collaboration with other CA GC partners (e.g., Los Angeles). CDPH and SFDPH will conduct a SF-Bay Area meeting with key local health jurisdiction partners to develop an ARG Regional Strategic Plan that includes best practices for ARG response.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of existing and newly developed case surveillance, epidemiology, and laboratory protocols with flow charts and definitions	Trang Nguyen until SFDPH GC Epidemiologist Coordinator hired	Sep 2016	Jul 2017
2	CA-SF GC RDR strategic plan for expansion of GC specimen collection and AST beyond SFCC GISP specimens	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
3	SF-Bay Area ARG Regional Strategic Plan	CDPH Regional GC RDR Coordinator	Oct 2016	May 2017

Strategy 1: New Activity #3

Name (500 Character Maximum):

Hire needed staff (such as surveillance and field epidemiologists, laboratorians, case investigators, and data entry personnel) to support local coordination and capacity

Implementation Plan (1000 Character Maximum):

SFDPH will additionally hire CA-SF GC RDR: microbiologist responsible for GC culture and AST, developing protocols including expanded culture and testing of new specimen sources and from new media (e.g., InTray from 3rd Street Youth Center and Clinic (YCC)); and 2 health workers to conduct partner services (PS) (one at SFCC, one embedded at 3rd St YCC to develop, implement, and evaluate PS protocols for youth). CDPH will additionally hire CA-SF GC RDR: regional health worker responsible for case investigation and partner follow-up of GC cases with reduced susceptibility outside SF, training and technical assistance to LHJs for investigations on ARG GC cases; and microbiologist to perform AST of GC isolates, communicate results to staff and LHJs, and initiate and coordinate the collection and storage of a repository of ARG isolates. CDPH/SFDPH will develop training protocols and evaluation methods.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Post and hire SFDPH positions	Susan Philip and Trang Nguyen	Aug 2016	Feb 2017
2	Post and hire CDPH positions	Heidi Bauer and Julie	Aug 2016	Feb 2017

		Stoltey		
3	CA-SF GC RDR staff training protocols and evaluation plans	SFDPH GC Epidemiologist Coordinator and CDPH Regional GC RDR Coordinator	Nov 2016	Feb 2017

Strategy 1: New Activity #4

Name (500 Character Maximum):

Advance workforce development and training related to rapid response for resistant GC (optional)

Implementation Plan (1000 Character Maximum):

SFDPH and CDPH staff with a role in ARG detection and response must be proficient in continuous quality improvement methods and standardized, applied problem solving. These skills are fundamental to every proposed ARG response activity and will increase SFDPH and CDPH workforce capacity for innovation by teaching standardized problem solving and evaluation to improve efficiency. CA-SF RDR hired and in-kind staff, as well as select SFDPH and CDPH clinicians, laboratorians, and health workers with roles in ARG detection and response, will undergo training on A3 Thinking to learn a common 'language' of problem solving. This method has already been taught at the SFDPH clinics and hospitals that will be partners in expanded GC culture efforts – proving further usefulness of ensuring this standard. Also, the CA STD/HIV Prevention Training Center (CAPTC), DIS Training Center (DISTC) will develop training materials for DIS on rapid response case investigation and partner services of ARG cases.

	2016 Milestones/Outputs (500 Characters Each)	**Person Responsible**	**Start Date**	**End Date**
1	Final A3 Thinking training schedule, contract, and staff attendee list	Susan Philip with Heidi Bauer	Aug 2016	Jul 2017
2	Identify CDPH or SFDPH staff to attend national STD and microbiology conferences for workforce development	Heidi Bauer and Susan Phillip	Aug 2016	Mar 2017
3	Training materials on rapid response case investigations and field services of ARG cases	CDPH Regional GC RDR Coordinator and CAPTC-DISTC	Oct 2016	Jul 2017

Strategy 2

Strategy: Enhance timely surveillance for detection of resistant GC threats

Add New Activity

Strategy 2: New Activity #1

Name (500 Character Maximum):

Establish local lab capacity and protocols for implementing e-test for timely antibiotic susceptibility testing

Implementation Plan (1000 Character Maximum):

In collaboration with the SFDPH GC EC, the SFDPH interim PHL Director Dr. Mark Pandori will work with the newly hired CA-SF GC RDR Microbiologist to update existing protocols for Etest for timely antibiotic susceptibility testing and protocols for providing results to clinicians in short time frames. PHL implemented Etest in 2011 and recently tested approximately 70 isolates per month for all CA GISP sites, but results have not yet been used to inform patient care. Again, the models of change and evaluation the lab staff, epidemiologists and DIS will be trained in will guide how this effort will be designed and evaluated. The CDPH MDL will continue to build capacity to conduct GC culture and AST with Etest. MDL will provide subject matter expertise and serve as a back-up and reference laboratory for additional testing of isolates from SFDPH. MDL will also maintain stock and surveillance cultures of notable ARG isolates for any future testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of existing and necessary protocols for Etest at PHL of SFCC GISP samples	Mark Pandori until SFDPH Microbiologist hired	Aug 2016	Oct 2016
2	Validated GC culture and Etest at CDPH MDL laboratory	Vishnu Chaturvedi until CDPH Microbiologist is hired	Aug 2016	Dec 2016
3	Number of antibiotic-resistant gonorrhea isolates archived at MDL	Vishnu Chaturvedi until CDPH Microbiologist is hired	Aug 2016	Jul 2017

Strategy 2: New Activity #2

Name (500 Character Maximum):

Develop processes for rapid communication of e-test results to surveillance and field epidemiology staff

Implementation Plan (1000 Character Maximum):

Importation of PHL results, including susceptibility data, into ISCHTR occurs routinely. Using the proposed training in standardized, applied problem solving, these processes will be automated and alerts developed to ensure timely use of critical Etest results for action (e.g., case investigation, verification of treatment to evaluate potential treatment failures). In collaboration with the CDPH Regional GC RDRC, the SFDPH GC EC will work with related SFDPH PHL, SFCC, epidemiology staff, and

CDPH staff to develop protocols and templates for rapid reporting of Etest results to appropriate SF and CA health workers and providers. The CDPH Regional GC RDRC will coordinate discussions to facilitate interoperability across SFDPH and CDPH IT systems to ensure seamless state and local data exchange and will work to operationalize real-time data transfer between CDPH MDL information systems and the existing CDPH ARG database.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Catalog of protocols and templates for rapid reporting of Etest results to SFDPH health workers and local providers	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2	Catalog of protocols and templates for communication of Etest results to CDPH regional health worker and regional providers	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3	Average turn-around-time for the collection and rapid reporting of ARG data fields from CDPH MDL laboratory information system to CDPH ARG database	CDPH Regional GC RDR Coordinator	Dec 2016	Jul 2017

Strategy 2: New Activity #3

Name (500 Character Maximum):

Increase and improve timeliness of reporting and complete capture of data relevant to antibiotic-resistant GC surveillance and epidemiology in electronic surveillance systems. These may include: treatment date and regimen, anatomic site of infection, gender of sexual partners

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC, in collaboration with the CDPH Regional GC RDRC, will finalize a list of key variables (e.g., treatment date and regimen, anatomic site of infection) to assess and prioritize projects to improve reporting timeliness and completeness, including the evaluation of sending electronic patient and laboratory data messages from providers such as the SFDPH outpatient clinics for importation to ISCHTR. The CDPH Regional GC RDRC will work within CDPH to facilitate SF providers' use of the California integrated communicable disease surveillance system, CalREDIE provider portal for rapid reporting and retrieval of GC treatment, and other relevant clinical data; evaluate a mechanism for rapid data exchange between CalREDIE and ISCHTR, including susceptibility data from PHL and MDL, and case/partner data for PS outside SF; and work to improve completeness of electronic laboratory reporting. This activity is linked to meeting requirements for Strategy 2: Activity #8.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date

1	List of key variables for ARG surveillance and epidemiology; timeline for evaluating and finalizing mechanisms to improve data completeness and timeliness	SFDPH GC Epidemiologist Coordinator with IT consultant	Sep 2016	Jul 2017
2	Determine the interoperability between SFDPH and CDPH electronic data systems to facilitate real-time sharing of relevant clinical data fields (i.e., treatment date and regimen, anatomic site of infection, gender of sexual partners)	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3			Select One	Select One

Strategy 2: New Activity #4

Name (500 Character Maximum):

Establish a plan for expanded collection of GC culture and performance of GC antibiotic susceptibility testing (e.g., collection of specimens from clinical sites outside of the STD clinic, collection of culture from female GC cases, collection of culture from extragenital sites of GC cases

Implementation Plan (1000 Character Maximum):

The SFDPH GC EC will collaborate with the CDPH Regional GC RDRC to create a timeline and protocols for collecting additional specimens at SFCC from females and extragenital sites (males and females) and at the 3rd Street YCC (with InTray) to attempt to isolate cultures and conduct Etests. During Year 1, SFDPH will increase the number of non-GISP specimens to culture from SFCC and 3rd St YCC, eventually trying to successfully culture isolates from an additional estimated 200 urethral, 50 cervical, 100 pharyngeal, and 100 rectal specimens, based on likely eligible patients using 2015 clinic data. Also, SFDPH will develop mechanisms to identify potential treatment failures and providers to target for expanded GC culture. Analyzing case report data might identify providers who should routinely collect cultures at the original and follow-up GC tests. CDPH MDL will provide GC culture and AST for Bay Area partners named by SF cases.

	2016 Milestones/Outputs (500 Characters Each)	**Person Responsible**	**Start Date**	**End Date**
1	Number of GC culture and Etest of non-GISP specimens from SFCC and 3rd St YCC	SFDPH GC Epidemiologist Coordinator	Nov 2016	Mar 2017
2	Catalog of protocols for Etest at PHL of SFCC and 3rd St YCC non-GISP specimens	Mark Pandori until SFDPH Microbiologist hired	Jan 2017	Jul 2017
3	Number of GC culture and Etest specimens tested from populations outside SF boundaries	Vishnu Chaturvedi until CDPH Microbiologist is hired	Jan 2017	Jul 2017

Strategy 2: New Activity #5

Name (500 Character Maximum):

Pilot novel approaches to detect resistance in non-STD clinic settings, including but not limited to public health detailing to distribute culture media plates (InTray GC™) to high-volume providers that do not routinely perform culture-based testing due to lab capacity issues.

Implementation Plan (1000 Character Maximum):

CDPH led an evaluation of InTray GC to culture male urethral specimens at SFCC and found that the InTray GC system was 87.5% sensitive for GC culture. SFDPH will collect specimens using InTray GC at the 3rd St YCC, benefitting from lessons learned to create protocols and an evaluation plan. Symptomatic female youth will be initially prioritized for culture; in 2015, 71 GC tests were conducted among symptomatic females ages <=25 (24 GC tests among symptomatic male youth). CA-SF GC RDR staff will analyze the yield of culture by InTray and the proportion of cultures that underwent AST with Etest, using results to plan expansion to other clinics. Additionally, the CDPH Regional GC RDRC will meet with large regional medical groups to discuss InTray GC/AST, and academic partners to explore piloting novel molecular assays to detect GC resistance.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Eligibility criteria and evaluation plan for GC culture collection using InTray and conducting Etest of 3rd St YCC specimens	SFDPH GC Epidemiologist Coordinator	Nov 2016	Mar 2017
2	Catalog of protocols for InTray specimen collection at 3rd St YCC	Mark Pandori until SFDPH Microbiologist hired	Jan 2017	Jul 2017
3	Number of meetings conducted with regional medical providers to discuss InTray GC and AST	CDPH Regional RDR Coordinator	Oct 2016	Jul 2017

Strategy 2: New Activity #6

Name (500 Character Maximum):

Package and ship specimens per protocols to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory agar dilution and molecular characterization, such as whole genome sequencing.

Implementation Plan (1000 Character Maximum):

SFDPH is committed to packaging and shipping of specimens per protocol to the appropriate Antibiotic-Resistant Lab Network (ARLN) laboratory for confirmatory testing and molecular characterization. Having participated in GISP since its inception, SFDPH has extensive experience in preparing inoculated culture plates from SFCC to the PHL for processing and shipment of frozen isolates to regional laboratories. SFDPH will be readily able to update existing protocols for shipment to

an ARLN laboratory for additional testing. While SFDPH will collaborate with CDC and other funded GC RDR sites on finalizing protocols and the proportion or types of specimens to send to an ARLN laboratory, SFDPH has estimated the proportion of GISP and non-GISP cultures from SFCC and 3rd St YCC that will be isolated and available for shipment to the ARLN, and its related costs. SFDPH will also package and ship a small number of isolates to CDPH MDL for additional reference testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Shipment protocols to ARLN	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2	Number of PHL staff trained on ARLN shipment protocols	SFDPH Microbiologist	Dec 2016	Jul 2017
3			Select One	Select One

Strategy 2: New Activity #7

Name (500 Character Maximum):

Electronically submit associated data to ARLN for addition of whole genome sequencing data, and for ultimate submission to CDC.

Implementation Plan (1000 Character Maximum):

Having a longstanding history of sending associated GC case and laboratory data to CDC as part of the GISP protocol, SFDPH will be readily able to update existing protocols and programming for electronic submission of required data to ARLN. SFDPH anticipates collaborating with CDC and other funded GC RDR sites on protocols and definitions. SFDPH will also continue to submit data to CDPH, per current protocols.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Data definitions and protocols for required GC RDR data to send to ARLN and CDC	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017
2	Data programming to send associated data to ARLN and CDC	SFDPH GC Epidemiologist Coordinator	Dec 2016	Jul 2017
3			Select One	Select One

Strategy 2: New Activity #8

Name (500 Character Maximum):

Enhance local health department capacity to appropriately record antibiotic susceptibility testing data

(e.g., date of test, test type, and MIC results by drug tested) in the state/local information system.

Implementation Plan (1000 Character Maximum):

Given its experience with Etest, the SFDPH PHL has a database for capturing all relevant AST data. These data were routinely uploaded and stored in ISCHTR. GISP results from the regional GISP laboratory are sent to SFDPH and stored in ISCHTR. The PHL database and ISCHTR will be evaluated and enhanced for interoperability and facile data exchange with CDPH as discussions with CDC and CDPH about testing and results variables lead to definitions and protocols for data-entry and quality assurance to implement. CDPH and SFDPH will evaluate mechanisms for sharing these data readily with surveillance and DIS. AST results will be added to existing state electronic laboratory reported data streams. Relevant ARG data fields (e.g., MIC) will be added to CalREDIE, and the existing CDPH ARG data system. CDPH will lead data system interoperability efforts across ISCHTR, CalREDIE, MDL laboratory information system and existing CDPH ARG database (in alignment with meeting Strategy 2: Activity #3).

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Updated database used by PHL for Etest and other AST results	SFDPH GC Epidemiologist Coordinator	Oct 2016	Mar 2017
2	AST results added to ELR data streams; relevant project data fields added to CalREDIE	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
3	Determine the interoperability between SFDPH and CDPH data systems to facilitate real-time data sharing of relevant laboratory data fields (i.e., date of test, test type, and MIC results by drug tested)	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017

Strategy 2: New Activity #9

Name (500 Character Maximum):

Evaluate time-to-clearance among persons tested and treated for GC who return for a test-of-cure (optional)

Implementation Plan (1000 Character Maximum):

San Francisco City Clinic has experience implementing an evaluation of GC molecular test of cure in men who have sex with men. Existing experience, protocols, and remaining questions will be built upon in future years of this grant to expand the evaluation of GC time to clearance in youth, females, and heterosexual males. Additional clinical sites would be considered within San Francisco and in other CA public health STD clinics (e.g., Orange County, San Diego). In addition, AST with Etest would also be considered to address correlation between time to clearance and antibiotic susceptibility profile. The

CDPH Regional GC RDR Coordinator would be responsible for planning the evaluation and coordinating with SF and other clinical sites in Year 1, to pursue the evaluation in subsequent project years.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	List of potential additional clinical sites within San Francisco to participate in time-to-clearance evaluation	SFDPH GC Epidemiologist Coordinator	Feb 2017	Jul 2017
2	GC time-to-clearance project plan	CDPH Regional GC RDR Coordinator	Nov 2016	Jul 2017
3			Select One	Select One

Strategy 3

Strategy: Enhance GC case investigations to identify transmission dynamics of emerging resistant GC threats

Add New Activity

Strategy 3: New Activity #1

Name (500 Character Maximum):

With CDC guidance, funded sites will draft and implement an unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility that encompasses areas of interest (e.g., travel history, anatomic sites of exposure)

Implementation Plan (1000 Character Maximum):

Based on the combination of the long history of SFDPH and CDPH participation in SSuN, SFDPH experience in interviewing GISP/Etest alert cases, and a CDPH draft protocol and instrument for ARG case investigation, CA-SF GC RDR will contribute extensive lessons learned and best practices to discussions with CDC and other RDR funded sites to finalize a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility. Our historic data collection from patients with GC, particularly with those who were contacted because of a GISP/Etest alert, will inform discussions on the quality and completeness of variables of interest, as well as how best to discuss public health concerns about antibiotic resistance in order to maximize the potential for new ARG cases to provide high quality information. The unified case investigation guide will be shared and built upon at a planned regional Bay Area meeting of ~20 key state and LHJ partners working on GISP and ARG efforts.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date

1	Data tables of relevant SFDPH SSuN and GISP data variables to inform discussion on a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility	SFDPH GC Epidemiologist Coordinator	Nov 2016	Jan 2017
2	Data tables of relevant CDPH SSuN and GISP data variables to inform discussion on a unified case investigation guide for resistant GC cases or GC cases with reduced susceptibility	CDPH Regional GC RDR Coordinator	Nov 2016	Jan 2017
3	Unified GC ARG case investigation guide	SFDPH GC Epidemiologist Coordinator and CDPH Regional GC RDR Coordinator	Nov 2016	Jul 2017
4			Select One	Select One
5			Select One	Select One

Strategy 3: New Activity #2

Name (500 Character Maximum):

Rapidly (within 2 days) interview all GC cases found through laboratory diagnostics or clinical presentation (e.g. unsuccessful treatment) to be infected with a strain of reduced-susceptibility GC.

Implementation Plan (1000 Character Maximum):

In San Francisco through 2015, all patients found to have an MIC above a GISP or Etest alert value were assigned for further interview, assessment of travel and antibiotic use, re-testing and partner notification. In 2015, all 14 cases with GISP alert values were assigned for interview within 24 hours; 10 of 14 cases were interviewed within 7 days, 4 of which were interviewed within 2 days. Local protocols will be evaluated and compared to CA GISP interview protocols to identify mechanisms that could be evaluated to increase timeliness and completeness of interviews. The CDPH regional health worker will rapidly interview all ARG cases that reside outside SF. Case assignment will initially begin with GC cases with reduced susceptibility or antibiotic resistance, but productivity and completeness of interviews will be continually monitored to determine how best to prioritize assigning other GC cases for interview (e.g., by gender of sex partner, HIV status, history of STD).

	2016 Milestones/Outputs (500 Characters Each)	**Person Responsible**	**Start Date**	**End Date**
1	Protocol for alerting staff of any cases requiring CA-SF GC RDR case investigation and partner services	Trang Nguyen until SFDPH GC Epidemiologist Coordinator hired	Aug 2016	Jul 2017

2	Evaluation plan to assess different modalities for CA-SF GC RDR case investigation and partner services	SFDPH GC Epidemiologist Coordinator and CDPH GC RDR Coordinator	Oct 2016	Jan 2017
3	Proportion of ARG cases residing in SF that were interviewed within 2 days among total number of ARG cases in SF	SFDPH Health Workers	Oct 2016	Jul 2017
4	Proportion of ARG cases residing outside of SF referred to CDPH regional health worker for interview within 2 days among total number of cases that reside outside of SF that are referred to the CDPH health worker for interview	CDPH Regional GC RDR Coordinator	Oct 2016	Jul 2017
5	Proportion of ARG cases residing outside SF that were interviewed within 2 days of assignment among total number of ARG cases residing outside SF that were assigned	CDPH Regional Health Worker	Oct 2016	Jul 2017

Strategy 3: New Activity #3

Name (500 Character Maximum):

Conduct investigations of sexual and social contacts and develop methods for describing social and sexual networks of interviewed cases.

Implementation Plan (1000 Character Maximum):

SFDPH has extensively enhanced its DIS program to integrate STD and HIV priorities and outcomes. Existing PS protocols for the CA-SF GC RDR will be enriched with CDPH expertise from other successful LHJ PS protocols. SFDPH will also develop a PS protocol for partners of youth at 3rd St YCC. Case and partner data are stored in ISCHTR in a way that has enabled actionable analysis of sexual networks. SFDPH will evaluate and enhance the way susceptibility and partnership data are collected, stored, and analyzed to assess different methods for describing social and sexual networks of GC cases. The CDPH regional health worker will provide PS for ARG cases outside SF, and CA and SF will build on existing expertise and analyses to characterize the regional sexual networks in order to enhance collaborative disease control efforts.

	2016 Milestones/Outputs (500 Characters Each)	**Person Responsible**	**Start Date**	**End Date**
1	Partner services protocol for GC cases with reduced susceptibility or antibiotic-resistant strains within SF	Trang Nguyen until SFDPH GC Epidemiologist Coordinator	Aug 2016	Feb 2017

2	Evaluation of ISCHTR data needs for enhancing social and sexual network analysis of GC cases with reduced susceptibility or antibiotic-resistant strains; updated data collection and routine analysis (ensuring continuous quality improvement) of social and sexual networks of GC cases with reduced susceptibility or antibiotic-resistant strains	Trang Nguyen until SFDPH GC Epidemiologist Coordinator	Aug 2016	Jul 2017
3	Proportion of interviews of partners of ARG cases that reside in SF among total number of partners of ARG cases identified in SF	SFDPH Health Workers	Nov 2016	Jul 2017
4	Partner services protocol for GC cases with reduced susceptibility or antibiotic-resistant strains outside SF, and across the SF-Bay Area Region	CDPH Regional GC RDR Coordinator	Oct 2016	Feb 2017
5	Proportion of interviews of partners of ARG cases that reside outside of SF among total number of partners of ARG cases identified outside of SF	CDPH Regional Health Worker	Nov 2016	Jul 2017

Strategy 3: New Activity #4

Name (500 Character Maximum):

Analyze phenotypic susceptibility testing, sociodemographic, risk behavior, and whole genome sequencing data (where available) concurrently to improve understanding of local GC epidemiology and transmission dynamics of emerging resistant GC threats.

Implementation Plan (1000 Character Maximum):

Existing SFDPH and CDPH systems will be updated to store Etest and ARLN data, including whole genome sequencing. SFDPH and CDPH will develop analytic plans in collaboration with CDC to determine the data elements and methods that will be useful to improving the local and regional epidemiology and transmission dynamics of emerging ARG threats. Because most GC patients for whom ARG data are available will have been identified through SFCC, we will have a rich dataset of sociodemographic and risk behavior data collected through medical care visits. Those patients able to be interviewed will have provided additional detail about risk behaviors, sexual partnerships, travel history, recent antibiotic use and meeting locations that will enrich the analyses. We anticipate having laboratory STD testing and AST results and sociodemographic data from a proportion of named contacts that we are able to reach, interview, and test, through SFDPH or CDPH PS and any MDL reference testing.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	List of data that will be reported from ARLN and added to local data systems	SFDPH GC Epidemiologist Coordinator	Jan 2017	Jul 2017
2	Analysis plan and draft table shells for SF epidemiology of emerging GC resistance	SFDPH GC Epidemiologist Coordinator and CDPH	Mar 2017	Jul 2017
3	Analysis plan and draft table shells for SF-Bay Area regional epidemiology of emerging GC resistance	Regional GC RDR Coordinator in collaboration with regional bay area counties	Mar 2017	Jul 2017
4			Select One	Select One
5			Select One	Select One

Strategy 3: New Activity #5

Name (500 Character Maximum):

Report all antibiotic susceptibility results and awardee-required variables to state health department and CDC and all susceptibility results demonstrating reduced susceptibility to state health department and CDC within 24 hours of testing.

Implementation Plan (1000 Character Maximum):

SFDPH has an extensive history with reporting data to CDPH and CDC in different formats, with reports using different visualizations and layouts (e.g., line lists, table summaries, pivot tables), and utilizing various mechanisms (e.g., CDC Secure Access Management Services, NETSS, CDPH secure file transfer), often in automated or routine modalities. ISCHTR already stores antibiotic susceptibility results provided by the regional GISP laboratory and Etest results from PHL. SFDPH routinely sends associated GC case and laboratory data to CDC as part of the GISP protocol. SFDPH will be readily able to update ISCHTR fields and update/prepare protocols and programming for electronic submission of required data to CDPH and CDC. SFDPH and CDPH will collaborate with CDC and other funded GC RDR sites to finalize unified protocols and definitions, which has been done as part of SSuN collaborative discussions.

	2016 Milestones/Outputs (500 Characters Each)	Person Responsible	Start Date	End Date
1	Data definitions and protocols for reporting of required antibiotic susceptibility test results and awardee-required variables to CDPH and CDC	SFDPH GC Epidemiologist Coordinator	Oct 2016	Jul 2017

2	Protocols and data programming to submit required case and susceptibility data to CDPH and CDC electronically within 24 hours of testing	SFDPH GC Epidemiologist Coordinator	Dec 2016	Jul 2017
3			Select One	Select One
4			Select One	Select One
5			Select One	Select One

Evaluation and Performance Measurement Strategy

Required performance measures for the project period are listed within this project's guidance in the 'CDC Evaluation and Performance Management Strategy' section. These are measures that awardees will be expected to report on in next year's progress report. The table below provides an opportunity for you to provide any baseline data that you may have – you are not expected to have data for all of these measures.

Strategy 2) Enhance timely surveillance for detection of resistant GC threats	
Number of trained personnel who can perform E-Test.	
Number of viable, non-viable, and contaminated specimens received by the local laboratory.	Viable: Non-Viable: Contaminated:
Number of isolates tested for antimicrobial resistance within proficiency standards.	
Number of clinical settings submitting specimens for antimicrobial resistance testing.	
Days from specimen collection to receipt at laboratory, from receipt at laboratory to e-Test completion, and from e-Test completion to report to clinician and local health department within the awardee-required timeframe.	Collection to Receipt: Receipt to E-Test Completion: E-Test Completion to Report:
Number and percentage of isolates found to have reduced susceptibility or resistance to antibiotics tested.	(Number) (%)
Number and percentage of GC lab reports received at the local health department through ELR with awardee-required	(Number) (%)

variables	
Strategy 3) Enhance GC case investigations to identify transmission dynamics of emerging resistant GC threats	
Number of reported GC cases to local health department with complete awardee-required demographic, epidemiologic and clinical variables.	3726
Number and percentage of resistant GC cases, GC cases with reduced susceptibility or GC treatment failure cases investigated within the awardee-required timeframe.	12 (Number) 92% (%)
Number and percentage of sexual and social contacts investigated of cases unidentified in #2 within the awardee-required timeframe.	0 (Number) 0% (%)
Number and percentage of isolates demonstrating reduced cephalosporin susceptibility reported to the state health department and CDC within 24 hours of testing	0 (Number) 0% (%)

Please describe the applicant's plan and ability to collect the necessary data and report on each of the measures listed in the guidance.

The *CA-SF GC RDR* proposal is poised to address CDC's evaluation and performance measures. SFDPH already has extensive experience in integrating both qualitative and quantitative data from epidemiological analyses, clinical preventive and testing services, field services, and case interviews to evaluate and improve programs, data collection, and surveillance. Baseline data for some of the requested performance measures are provided to reflect SFDPH's current capacity to meet project objectives.

SFDPH and CDPH will prepare a list of qualified personnel hired or retained to support grant activities to meet Strategy 1.

SFDPH and CDPH will report on metrics to demonstrate how this work has enhanced timely surveillance for detection of resistant GC threats to meet Strategy 2. As part of GISP, SFDPH and CDPH have had to routinely report evaluation and performance metrics similar to the ones requested for this strategy. A table of recently reported SF GISP process measures is provided as an example:

Table 1. Example SF GISP Process Measures	Jan 1–Dec 31, 2014 No./%	Jan 1–June 30, 2015 No./%
Number of SF isolates submitted to the GISP regional laboratory	322 (74%)	160 (79%)
Percentage of submitted SF isolates that were found by the GISP regional laboratory to be non-viable or contaminated	1 (0.3%)	0 (0%)
Percentage of monthly SF isolate batches that were shipped to the GISP regional laboratory within one week after the end of monthly collection	2 (33%)	1 (17%)
Percentage of monthly SF demographic/clinical data transmissions that were submitted to CDC within one month of the completion of specimen collection	100%	100%
Percentage of collected SF isolates for which the following data elements were reported:		
Gender of sex partner/sexual orientation	98%	99%
HIV status	98%	93%
Treatment	89%	97%

Evaluation of performance metrics for Strategy 3, enhancing GC case investigations to identify transmission dynamics of emerging resistant GC threats, will be readily and routinely conducted using existing fields in ISCHTR, which can be seamlessly modified to account for any additional metrics required by CDC. Because ISCHTR integrates STD surveillance data with electronic medical record data from SFCC, field investigations, and all STD testing conducted by the PHL, data can be extracted from ISCHTR to evaluate data by STD test, person, or isolate. CDPH data systems (CalREDIE and the existing ARG database) will be modified to account for any requested evaluation metrics that are not accounted for by existing data fields.

SFDPH and CDPH will plan to monitor and report, as requested by ELC/CDC. SFDPH and CDPH will collaborate with ELC/CDC on the development of additional performance measurements, as appropriate.