

# Gonococcal Isolate Surveillance Project (GISP)

## Protocol

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(Web version)



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Centers for Disease Control and Prevention



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## Background

The treatment and control of *Neisseria gonorrhoeae* infections have been complicated by the organism's ability to acquire antimicrobial resistance. The development of plasmid-mediated resistance to tetracycline, i.e., TetM, caused CDC to recommend, in 1985, that tetracycline not be used for the treatment of gonococcal infections. The increasing prevalence of strains with plasmid-mediated resistance to penicillin (PPNG) prompted the abandonment of penicillins as single-dose therapies for gonorrhea in 1987. The prevalence of chromosomally-mediated resistance to fluoroquinolones in *N. gonorrhoeae* in Hawaii and California reached levels at which fluoroquinolones were no longer recommended for gonorrhea treatment in Hawaii in 2000 and in California in 2002. Occasional chromosomal-mediated resistance to spectinomycin has also been reported. Sporadic isolates with high minimal inhibitory concentrations (MICs) to azithromycin and cefixime have emerged more recently.

The Gonococcal Isolate Surveillance Project (GISP) was established in 1986 to monitor trends in antimicrobial susceptibilities of strains of *N. gonorrhoeae* in the United States and to establish a rational basis for the selection of gonococcal therapies. Data from this project have been reported and used to revise the CDC's STD Treatment recommendations in 1989, 1993, 1998, 2002, and 2006. This protocol supersedes all previous protocols for the project.

## Objectives

1. To monitor trends in antimicrobial susceptibilities in *N. gonorrhoeae*.
2. To characterize male patients with gonorrhea, particularly those infected with *N. gonorrhoeae* that are not susceptible to recommended antimicrobials.
3. To phenotypically characterize antimicrobial-resistant isolates to describe the diversity of antimicrobial resistance in *N. gonorrhoeae*.

## Methods

The Gonococcal Isolate Surveillance Project is a collaborative project between the CDC (Epidemiology and Surveillance Branch [ESB] and Statistics and Data Management Branch [SDMB] with support from the Program and Training Branch [PTB], Division of STD Prevention [DSTDP], National Center for HIV, Hepatitis, STD, and TB Prevention [NCHHSTP], and the Laboratory Reference and Research Branch [LRRB]), four regional laboratories, and selected sentinel STD clinics in the United States. The responsibilities of each group of participants are detailed in this protocol.

GISP analyses are based on (a) demographic and clinical data from the first 25-30 male patients attending the sentinel clinics each month who have been identified to have a positive urethral culture for *N. gonorrhoeae*, and (b) antimicrobial susceptibility data from these urethral isolates.

## **Sentinel Site Activities and Responsibilities**

A GISP Sentinel Site is responsible for the monthly submission of (a) male urethral gonococcal isolates to its assigned GISP Regional Laboratory, and (b) clinical/demographic data on GISP patients to CDC.

To participate in GISP, those sentinel STD clinics that regularly use non-culture methods for gonococcal testing can routinely use gonococcal culture in lieu of or in addition to non-culture testing on all or a subset of patients. Culture provides useful data (i.e., data on antimicrobial susceptibility) that can benefit patients directly and is important for local disease control efforts.

At each Sentinel Site, an individual will be assigned to be responsible for data collection and appropriate gonococcal isolate collection, and to ensure that the isolates are sent to the Regional Laboratories and the epidemiologic data are sent to CDC.

### ***Sentinel Site Laboratory Activities***

#### **Isolate Collection, Handling, and Shipping**

1. Urethral isolates of *N. gonorrhoeae* (based on a presumptive\* or confirmed identification) will be collected from the first 25 men with urethral gonococcal infection (regardless of symptom status) each month. Usually, the isolates will be collected starting on the Monday of the first full week each month.

Because there may be occasional month to month variability in the number of isolates submitted, a sentinel site may provide >25 isolates in any given month to make up for providing <25 isolates in other months; the overall goal is for each sentinel site to provide at least 300 isolates per year. Most isolates will be pre-treatment isolates; however, post-treatment isolates may be included in the sample.

\*A presumptive identification of *N. gonorrhoeae* will be based on the following criteria: (i) growth of typical appearing colonies on a selective medium such as Thayer-Martin at 35 C to 36.5 C in 5% CO<sub>2</sub>, (ii) a positive oxidase test, and (iii) the observation of gram-negative, oxidase-positive diplococci in stained smears.

2. Gonococcal isolates will be subcultured from the selective primary medium to a noninhibitory medium, e.g., chocolate agar with 1% IsoVitaleX to obtain a pure culture of the isolate. If the subcultured isolate is not pure, serial subcultures of individual colonies must be performed until a pure culture is obtained. After 18 to 20 h. incubation, growth from the pure culture is suspended heavily in trypticase soy broth containing 20% (v/v) glycerol; duplicate frozen cultures of each isolate are prepared.

3. Isolates will be assigned sequential identifiers for each month. Each identifier will be composed of a three-letter designation for the Sentinel Site, followed by a six-digit number indicating the year and month of isolate collection (yyyymm), and a two digit number in the sequence from 01 through 25 or higher. For example, the 20th isolate selected in January 2003 in Atlanta will be given the number ATL-200301-20.

Each Sentinel Site laboratory should maintain a monthly log of GISP identification numbers and the corresponding patient name or identification number. This log is for local use only and is not shared with the Regional Laboratory or CDC. This information must be routinely shared with the Sentinel Site staff person who is responsible for abstracting demographic and clinical data on GISP patients.

4. Isolates will be frozen to -70 C if possible. If a -70 C freezer is not available, isolates may be frozen to -20 C (freezer/dry ice chest) until shipped to the Regional Laboratory; isolates to be shipped must be placed in the coldest sections of the -20 C freezer (not in the door or at the front of a shelf) and should be stored in containers separate from any other frozen gonococcal cultures (including separate from duplicate frozen specimens). GISP isolates should not be subjected to changes in temperature as they may result in loss of viability during storage. A frost-free freezer should not be used.
5. Isolates should be shipped each month to the Regional Laboratory on Monday of the week immediately following completion of collection of the isolates but no later than the first Monday of the month following the month of isolate collection. Duplicate isolates must be kept until the Regional Laboratory confirms that viable isolates have been received.

\*Please e-mail or telephone the Regional Laboratory **prior** to shipping the strains to confirm when the strains will be shipped and to ensure that someone in the Regional Laboratory will be available to receive the strains. Ideally, isolates should be shipped no later than Wednesday in any week in which they are shipped to ensure that they are received at the Regional Laboratory before close of business on Friday.

Isolates must be packed in two leak-proof containers, one inside the other. The package containing the isolates should be packed in insulated styrofoam containers (to be provided by the Regional Laboratory) with dry ice (at least 10 lb); dry ice should be packed on each side of the package of isolates. Ship the container by overnight express, charging the shipping costs to the account number provided by the Regional Laboratory. The container will be returned to the Sentinel Site by regular package delivery for future shipments. Sites should ship GISP isolates **each month**; isolates should not accumulate for several months and then be shipped together because this prevents the Regional Laboratories from completing the susceptibility testing on schedule.

## *Sentinel Site Clinic or Program Activities*

### **Reporting of Demographic and Clinical Data**

#### ***Patient Data***

Demographic and clinical data should be submitted for each patient from whom a GISP isolate is submitted. A unique GISP number will be assigned to each patient (see Isolate Collection, item 3 above). Data may be obtained through review of medical records by clinic staff. Data will be submitted electronically using Form 1 (CDC 73.60 A) of the secure GISP-web based application and maintained locally in the clinic files (see Appendix 1 for description of Data Elements). Data may also be submitted in electronic form using Epi Info data entry files provided by the GISP Data Manager. Demographic and clinical data reports should be received at CDC *no more than four weeks* after the end of the month in which the corresponding isolates were collected.

Appendix 1 provides detailed descriptions of the data elements. The GISP Coding Guide provides instructions on correct coding of responses. The following is a concise list of the demographic and clinical data to be collected:

- Sentinel site code
- Sequential patient number (01- 25 or higher)
- Clinic code (for those Sentinel Sites submitting GISP isolates from more than one clinic)
- Sex
- Ethnicity
- Race (census categories)
- Date of clinic visit
- Date of birth
- Age
- Sexual orientation
- Symptoms
- Reason for clinic visit
- Previous history of gonorrhea
- Number of previous confirmed episodes of gonorrhea in past year
- Zip code
- Most recent known HIV status at clinic visit for gonorrhea
- Travel outside the state where the sentinel site is located
- History of giving or receiving drugs / money for sex in the previous 60 days
- Any antibiotic use during the previous 60 days
- History of injection drug use in the previous 60 days
- History of noninjection recreational drug use (excluding alcohol) in the previous 60 days
- Primary treatment (for gonorrhea); for Other Treatment 1 (if drug not listed): write in the name of the alternative primary antimicrobial therapy for gonorrhea
- Secondary treatment (co-treatment for presumed chlamydia)

### ***Clinic Data***

As part of monthly GISP data submission, each Sentinel Site will also submit the total number of episodes of gonorrhea that were diagnosed at the clinic in the current or previous month, as well as the subtotals of the number of episodes of gonorrhea diagnosed in men and in women. For sites with more than one clinic submitting isolates to GISP, the sum of totals for all contributing clinics should be submitted.

### ***Sentinel Site Annual Reporting for Annual Funding***

Sentinel Sites should report annually, in the Comprehensive STD Prevention Services (CSPS) grant application, on the following items:

1. Enrollment strategy: Is GISP capturing the first 25 men with urethral gonorrhea seen at the clinic each month? (Are all men cultured, whether symptomatic or asymptomatic, or are selected men cultured? Is the sample defined by the first 25 positive cultures, and not by Gram stains or other ways?);
2. Percentage of isolates which are (a) dead or (b) contaminated (list separately) on receipt at the Regional Laboratory (will be reported to Sentinel Sites by Regional Laboratories);
3. Percentage of clinical and demographic data that is incomplete or missing (will be reported to Sentinel Site by GISP Data Manager);
4. Timeliness of isolate and data submission (isolates should be shipped to lab within 1 week after end of collection and data should be sent within 4 weeks after end of month in which corresponding isolates are collected);
5. Laboratory procedures for isolate processing prior to shipping;
6. Storage of duplicate isolates until Regional Laboratory confirms that viable isolates have been received.

## **Regional Laboratory Activities and Responsibilities**

The Regional Laboratories in Atlanta, Birmingham, Cleveland, and Seattle are responsible for determining  $\beta$ -lactamase production and antimicrobial susceptibilities of GISP isolates received from the Sentinel Sites.

**Receipt of Isolates:** The isolates will be cataloged and frozen at -70 C until tested. Any problems with the isolates such as improper shipping, nonviability, or contamination should be reported as soon as possible to the Sentinel Site and to CDC. The insulated containers will be returned to the Sentinel Sites for future shipments by regular mail.

**Confirmatory Testing:** The Regional Laboratories are not required to perform confirmatory tests on all isolates although it is recommended that confirmatory tests be performed on any isolate that exhibits atypical colonial morphologic characteristics or aberrant susceptibility patterns. Because we are testing only urethral isolates, we do not anticipate a significant problem with the inclusion of nongonococcal isolates in the sample. However, occasionally, urethral *N. meningitidis* isolates may be isolated, rather than *N. gonorrhoeae*. Because gonococcal serologic reagents may cross-react with nongonococcal *Neisseria* and related species, we recommend that strains be identified with tests that detect acid production from carbohydrates and/or enzyme substrate tests or with a probe culture confirmation test.

**$\beta$ -lactamase Tests:** All isolates will be tested for  $\beta$ -lactamase by the Nitrocefin test (Appendix 2).

**Antimicrobial Susceptibility Testing:** Antimicrobial susceptibilities (minimal inhibitory concentrations, MICs) to penicillin G, tetracycline, spectinomycin, cefixime, cefpodoxime, ceftriaxone, ciprofloxacin, and azithromycin will be determined by the agar-dilution procedure on Difco GC medium base (Becton Dickinson, Cockeysville, MD) inoculated with  $10^4$  colony forming units (CFU) (see Appendix 3). Regional Laboratories should include a set of control strains (F-18 [ATCC 49226; quality control isolate mandated on the National Committee on Clinical Laboratory Standards (NCCLS)], F-28, P681E, CDC 10328, CDC 10329, SPJ-15, and SPL-4) with each run and should report control strain MIC data on Form 3 (CDC 73.60C) each month (see Appendix 4, CDC Reference Strains of *N. gonorrhoeae*). The results of Form 3 should be entered into the GISP web-based application and the receipt copy should be maintained in laboratory files (see Appendix 1 for description of Data Elements, Form 3 or CDC 73.60C). It is expected that susceptibility testing will be completed within one month of receipt of isolates from a Sentinel Site, and reported to CDC on a monthly basis within one week of completion.

If isolates meeting Alert Value MIC criteria as listed below are identified, it is the responsibility of the Regional Laboratory to retest these isolates to confirm the high MICs. Regional Laboratory personnel may retest these isolates with the next batch of isolates, provided this is no longer than one month after the initial test.

### Isolates with Alert Value MICs

Isolates with the following MICs require confirmation by retesting:

Ceftriaxone MIC  $\geq 0.125$   $\mu\text{g/ml}$   
Cefpodoxime MIC  $\geq 0.25$   $\mu\text{g/ml}$   
Cefixime MIC  $\geq 0.25$   $\mu\text{g/ml}$

For ceftriaxone, cefpodoxime, and cefixime, isolates should be tested for growth on medium containing the antibiotics at concentrations ranging from two dilutions below the initial MIC to sufficient concentrations above the initial MIC to obtain an endpoint MIC.

Ciprofloxacin MIC  $\geq 1.0$   $\mu\text{g/ml}$

For ciprofloxacin, isolates should be tested for growth on medium containing two-fold dilutions of ciprofloxacin up to, and including, a concentration of ciprofloxacin that will provide an endpoint MIC.

Azithromycin MIC  $\geq 2.0$   $\mu\text{g/ml}$

For azithromycin, isolates should be tested for growth on medium containing azithromycin at concentrations ranging from two dilutions below the initial MIC to sufficient concentrations above the initial MIC to obtain an endpoint MIC.

Spectinomycin MIC  $> 128$   $\mu\text{g/ml}$

For spectinomycin, isolates should be retested for growth on 128.0  $\mu\text{g/ml}$  of spectinomycin.

The GISP Coordinator and Project Manager at CDC, sentinel site, and the pertinent local and/or state STD programs should be notified **within one working day** by telephone or by e-mail of any isolate(s) identified to have a high MIC. If the alert isolate(s) is re-tested, the GISP Coordinator and Project Manager at CDC, sentinel site, and the pertinent local and/or state STD programs should be notified **within one working day** after the alert value(s) has been confirmed. Such isolates also should be shipped rapidly in *triplicate* to **CASPIR, CDC**; laboratory personnel should not wait until the request lists arrive from CDC to ship these isolates. A sheet marked "Alert Value Isolate Packing Form" that contains the original and the retest MIC values for each isolate should be included with the isolate shipment; a copy of this same sheet should **also** be sent separately to the GISP Coordinator.

**Isolate Preservation:** All isolates should be suspended in trypticase soy broth containing 20% (v/v) glycerol and frozen at  $-70$  C in duplicate at the Regional Laboratories. When isolates are requested by CDC for further characterization, *triplicate* copies of each requested isolate should be shipped to **CASPIR, CDC**. A copy of each shipped isolate must be maintained at the Regional Laboratory until notified by the GISP Coordinator or GISP Manager that the isolates have been received. This will generally require maintenance of isolates from the current year and the previous year.

**Shipping isolates to CASPIR:**

When preparing GISP specimens for shipment to CASPIR, please put specimens into **liquid nitrogen suitable cryotubes with screwcaps** (no snapcaps). GISP isolates should be shipped to:

Robert J. Davidson  
CDC CASPIR™ (CDC and ATSDR Specimen Packaging, Inventory and Repository) Facility  
602 Webb Gin House Rd., Bldg. C  
Lawrenceville, GA 30045  
tel: 770-339-5942  
fax: 770-339-5943  
e-mail: [RMabe@cdc.gov](mailto:RMabe@cdc.gov)

GISP isolates should be shipped on Mondays or Tuesdays using FedEx. At the time that a GISP shipment is sent, Robert Davidson should be e-mailed with the date of shipment and the FedEx tracking number so that he can expect and monitor the shipment.

**Data reporting:** Upon completion of laboratory testing, the antimicrobial susceptibilities for isolates submitted from each Sentinel Site will be entered in the GISP web-based application (see Appendix 1 for data elements for Form 2, CDC 73.60 B). Instructions for coding are found in the GISP Coding Guide. The results of Form 2 should be entered into the GISP web-based application and the receipt copy of Form 2 should be maintained in the laboratory files. A copy of the results of Form 2 should also be sent back to their respective sentinel sites.

**External Quality Assessment (EQA, formerly known as Proficiency Testing):** Twice each year, in November and May, a set of 15 coded cultures will be provided to the Regional Laboratories by NCHHSTP/DSTD/LRRB, CDC for antimicrobial susceptibility testing. These cultures will include strains selected to represent susceptible and resistant isolates of *N. gonorrhoeae* and may include more than one copy of some strains. Isolates should be tested and results reported to CDC by February 15 (for cultures provided in November) and by August 15 (for cultures provided in May). NCHHSTP/DSTD/LRRB, CDC will report back to each Regional Laboratory within 30 days of receiving results from each site with a preliminary discussion of results to allow the Regional Laboratory to assess its intralaboratory reproducibility. Some assessment of overall performance may be based on previously determined modal MICs for strains. Each preliminary report will indicate individual MICs that are  $\geq 2$  dilutions greater or less than the previously determined modal MIC for that strain and antimicrobial agent. If the EQA results suggest problems in MIC testing, the Regional Laboratory should identify and address these problems, and report to CDC (NCHHSTP/DSTD/LRRB) on corrections made. This report should be made within 30 days of notification by CDC that corrective actions are necessary. Depending upon the extent of testing problems, a second set of EQA cultures may then be provided for testing, with another 60 days for completion. Customized testing procedures may be used to address specific testing difficulties. Finally, if proficiency problems cannot be solved, testing may have to be shifted to an alternate laboratory.

**Training and Consultation for Sentinel Sites:** The Regional Laboratories may need to perform training of Sentinel Site personnel or provide technical assistance consultation to Sentinel Sites to improve or optimize the quality of GISP isolates submitted. To assist Sentinel Sites in addressing any problems with isolate storage or shipment, Regional Laboratories will be asked to report annually to each of their Sites the number and percentage of isolates that were (a) nonviable or (b) grossly contaminated with other organisms. If a problem with nonviability or contamination is recognized by the Regional Laboratory, this should be brought to the attention of the Sentinel Site immediately, without waiting for the annual reporting.

### ***Regional Laboratory Annual Reporting for Annual Funding***

In addition to annual reporting to the Sentinel Sites as described above, Regional Laboratories should report annually, in the Cooperative Agreement (PS09- 901) Interim Progress Report application, on the following items:

1. Timeliness of isolate testing (should be completed within 30 days of receipt) and of Form 2 data submission to CDC (should be on monthly basis).
2. Storage of duplicate isolates when isolates are requested by CDC, in case any follow-up testing at the Regional Laboratory is needed.
3. Use of control strains and reporting of control strain MIC data on Form 3.
4. Proficiency testing results.
5. Timeliness of CASPIR isolate submission.

## **Centers for Disease Control and Prevention Activities and Responsibilities**

The administrative duties and technical assistance responsibilities relating to GISP will be performed in ESB, SDMB, PTB, and LRRB, DSTDP, NCHHSTP.

### **Description of DSTDP, NCHHSTP Activities (ESB, SDMB, PTB):**

1. Perform site visits, as needed, to Sentinel Sites and Regional Laboratories.
2. Implement data collection protocols, including modification of data collection forms when necessary and complying with Office of Management and Budget requirements. Perform data management. Provide annual report to each Sentinel Site describing what percentage of the Sentinel Site data are incomplete or missing.
3. Perform review and analysis of demographic, clinical, and antimicrobial susceptibility data. Communicate important clinical findings to STD programs.
4. Prepare and distribute regional and site-specific data in electronic format to sites participating in GISP on a per request basis.
5. Prepare and distribute annual report summarizing project findings.
6. Request GISP isolates from Regional Laboratories for archival storage in CASPIR.
7. Evaluate and fund budget requests from Sentinel Sites and Regional Laboratories.
8. Recruit new sites as needed.
9. Address human subjects issues for the project.

### **Description of LRRB Activities:**

1. Train Regional Laboratory personnel when necessary.
2. Select, quality control, evaluate, and distribute to Regional Laboratories (a) Difco GC medium base for antimicrobial susceptibility testing, (b) antimicrobial powders that do not require Material Transfer Agreements (e.g., penicillin, spectinomycin, etc.), and (c) control strains.
3. Confirm antimicrobial susceptibility results for isolates with Alert Value MICs, and other isolates as needed, and provide MICs to GISP Coordinator within 4 weeks of receipt of isolates in LRRB.
4. In consultation with the GISP Coordinator, distribute External Quality Assessment (EQA) cultures twice annually. Prepare and distribute annual EQA report.
5. Perform molecular epidemiologic characterization of selected isolates (PPNG, TRNG, PPNG/TRNG, spectinomycin-resistant isolates, isolates with intermediate resistance or resistance to ciprofloxacin [MIC  $\geq$  0.125  $\mu$ g/ml], or isolates with MICs  $\geq$  2.0  $\mu$ g/ml of

azithromycin, isolates with MICs  $\geq 0.25$   $\mu\text{g/ml}$  of cefixime or ceftriaxone, and others as deemed appropriate).

6. Perform identification of novel antimicrobial susceptibility patterns among isolates that require further investigation.

## **General Project Issues**

### **Quality Assurance**

It is expected that Sentinel Sites, Regional Laboratories, and CDC will perform the tasks described in this protocol in a timely and efficient manner within the prescribed deadlines. A summary of the GISP timelines for project participants may be found in Appendix 8. Difficulties in adhering to the protocol with regards to isolate collection at the Sentinel Sites should be reported to the Regional Laboratories; difficulties in adhering to the protocol with regards to clinical/demographic data collection at the Sentinel Sites and difficulties in adhering to the protocol at the Regional Laboratories should be referred to the GISP Coordinator at CDC.

The duties listed in this protocol for the various GISP participants may overlap in many areas. Frequent communications among Principal Investigators, Co-Investigators, and Associates are to be conducted to monitor the day-to-day activities of the project. On an annual basis, a meeting of the Principal Investigators and the Co-Investigators will take place. Additional meetings are to be scheduled as required.

### **Human Subjects**

The GISP protocol was reviewed by the Associate Director for Science (ADS) of the NCHHSTP, CDC, in August 2010 and was determined not to require CDC Institutional Review Board (IRB) review because the project activity is surveillance, a disease control activity, and not research.

### **Publication of GISP Data**

In order to make GISP data widely available, CDC will publish an annual GISP report as well as other GISP reports and peer-reviewed manuscripts as needed. Local and regional use of GISP data is encouraged. Any draft manuscripts that describe GISP data or GISP isolates should be distributed to all GISP investigators for review and comment prior to submission for local and CDC clearance and publication. Comments from GISP investigators should be provided to authors within two weeks of receipt of the manuscript after which, if comments are not received by authors, it will be assumed that recipients have no concerns regarding the content and the authors are free to submit the manuscript for appropriate clearances and publication. If the paper describes data analysis for a specific individual Sentinel Site or an outbreak investigation at a specific Sentinel Site or Sites, involvement of Sentinel Site staff with the paper is necessary.

### **Use of GISP Isolates and GISP Data**

GISP isolates are collected primarily for the purposes stated in the GISP protocol, but some uses of GISP isolates and GISP data not described in this protocol may be desirable and may enhance the public health usefulness of this project. To ensure adequate communication and address any human subjects issues which may arise with the use of isolates or data collected for public health surveillance, proposals for uses of GISP isolates or GISP data not described in this protocol should be initiated through the following process: 1) a brief (i.e., 1-2 page) written proposal should be provided to the GISP Coordinator for CDC review, 2) consent and/or collaboration of the appropriate Sentinel Site state or local STD programs that provided the isolates should be obtained, and 3) Institutional Review Board (IRB) review should be sought as appropriate. Submission of the proposal to the GISP Coordinator at CDC is requested as a first step to ensure that projects do not overlap with work already in progress and to allow assessment for human subjects determination at CDC.

An exception to this process is when isolates are already collected dually under GISP and another ongoing protocol. In that case, appropriate consents and/or collaborations of the persons collecting and processing the isolates should already have been obtained. Local IRB review should be sought as appropriate.

### **Selection Criteria for Project Expansion**

The GISP system may be expanded to include additional geographic sites; these sites will be chosen based on geographic location, patient population characteristics, clinic operating procedures, clinic volume, and the ability of the clinic and laboratory personnel to adhere to the technical and time-limit requirements of the protocol.

## Appendix 1

### GISP Data Elements

#### Demographic/Clinical Data (Form1 or CDC 73.60A)

Variable Name	Type/Length	Description	Values
CLINIC	[Char, 3]	Sentinel site code	ALB=Albuquerque, ATL=Atlanta, BAL=Baltimore, BHM=Birmingham, CHI=Chicago, CIN=Cincinnati, CLE=Cleveland, DAL=Dallas, DEN=Denver, DTR=Detroit, GRB=Greensboro, HON=Honolulu, KCY=Kansas City, LAX=Los Angeles, LBC=Long Beach, LVG=Las Vegas, MIA=Miami, MIN=Minneapolis, NOR=New Orleans, NYC=New York City, OKC=Oklahoma City, ORA=Orange County, PHI=Philadelphia, PHX=Phoenix, POR=Portland, SDG=San Diego, SEA=Seattle, SFO=San Francisco, TRP=Tripler Army Medical Center
YRMO	[Char, 6]	Year/Month of patient's visit	YYYYMM
TOTYRMO	[Char, 6]	Year/Month of clinic totals for gonorrhea	YYYYMM
EPFEM	[Num, 3]	total monthly female gonorrhea episodes	
EPMALE	[Num, 3]	total monthly male gonorrhea episodes	
TOTEP	[Num, 3]	total monthly gonorrhea episodes	
ID	[Char, 2]	patient or isolate number	01, 02, 03, ... 30 or higher
CLINID	[Char, 1]	clinic identifier number	
SEX	[Char, 1]	gender	1=male, 2=female, 9=unknown
ETHNIC	[Char, 1]	Hispanic origin	1=Hispanic, 2=non-Hispanic, 9=Unknown
AMIND	[Char, 1]	American Indian/ Alaskan Native	1= yes, 2= no
ASIAN	[Char, 1]	Asian	1= yes, 2= no
BLACK	[Char, 1]	Black	1= yes, 2= no
NAHAW	[Char, 1]	Native Hawaiian/ Pacific Islander	1= yes, 2= no

<b>Variable Name</b>	<b>Type/Length</b>	<b>Description</b>	<b>Values</b>
WHITE	[Char, 1]	White	1= yes, 2= no
ORACE	[Char, 1]	Other race	1= yes, 2= no
DATEVIS	[Date, 10]	date of clinic visit	MM/DD/YYYY
DOB	[Date, 10]	date of birth	MM/DD/YYYY
AGE	[Num, 2]	age in years	
SEXOR	[Char, 1]	sexual orientation	1= heterosexual, 2= homosexual, 3=bisexual, 9= unknown
SYMP	[Char, 1]	symptoms of gonorrhea	1= discharge and/or dysuria, 2= no discharge or dysuria, 9= symptoms unknown
REASON	[Char, 1]	reason for clinic visit	1=volunteer, 2=contact of gonorrhea patient, 3=test of cure, 8=other, 9=unknown
HISTORY	[Char, 1]	previous history of gonorrhea	1=yes, 2=no, 9=unknown
EPSDS	[Num, 2]	number of previous episodes within the past 12 months	0=no documented previous episodes in the past 12 months 99=unknown (patient record not available)
ZIP	[Char, 5]	zip code (residential)	00000=homeless, 99999=unknown
HIVSTAT	[Char, 1]	most recent known HIV status at clinic visit for gonorrhea	1=positive, 2=negative, 3=indeterminate, 9=unknown
TRAVEL	[Char, 1]	travel outside the state where the sentinel site is located in the previous 60 days	1=yes, 2=no, 9=unknown
SEXWK	[Char, 1]	history of giving or receiving drugs/money for sex in the previous 60 days	1=yes, 2=no, 9=unknown
ANTIBIOT	[Char, 1]	any antibiotic use during the previous 60 days	1=yes, 2=no, 9=unknown
IDU	[Char, 1]	history of injection drug use in previous 60 days	1=yes, 2=no, 9=unknown
NONIDU	[Char, 1]	history of noninjection recreational drug use (excluding alcohol) in the previous 60 days	1=yes, 2=no, 9=unknown

Variable Name	Type/Length	Description	Values
TRMT1	[Char, 2]	primary treatment for gonorrhea	00=none, 03=spectinomycin (Trobicin) 2 g, 04=ceftriaxone (Rocephin) 250 mg, 05=ceftriaxone (Rocephin) 125 mg, 06=ciprofloxacin (Cipro) 500 mg, 07=cefoxitin (Mefoxin) 2 g, 12=cefixime (Suprax) 400 mg, 14=cefpodoxime proxetil (Vantin) 200 mg, 15=ofloxacin (Floxin) 400 mg, 17=ceftizoxime (Cefizox) 500 mg, 18=cefotaxime (Claforan) 500 mg, 21=azithromycin (Zithromax) 2 g, 22=levofloxacin (Levaquin) 250 mg, 23=cefpodoxime proxetil (Vantin) 400 mg, 24=ceftibuten (Cedax) 400 mg, 25=cefdinir (Omnicef) 300 mg, 26=cefdinir (Omnicef) 600 mg, 88=other (please indicate in othtrmt1), 99=unknown
OTHTRMT1	[Char, 15]	alternative primary therapy for gonorrhea	
TRMT2	[Char, 2]	treatment for presumptive chlamydial coinfection	00=none, 01=ampicillin/amoxicillin, 09=doxycycline (Vibramycin)/tetracycline, 10=erythromycin, 11=azithromycin (Zithromax) 1 gm, 15=ofloxacin (Floxin), 88=other, 99=unknown

## Appendix 1 (Continued)

### GISP Data Elements

#### Antimicrobial Susceptibility Testing (Form 2 or CDC 73.60B)

Variable Name	Type/Length	Description	Values
CLINIC	[Char, 3]	Sentinel site code	ALB=Albuquerque, ATL=Atlanta, BAL=Baltimore, BHM=Birmingham, CHI=Chicago, CIN=Cincinnati, CLE=Cleveland, DAL=Dallas, DEN=Denver, DTR=Detroit, GRB=Greensboro, HON=Honolulu, KCY=Kansas City, LAX=Los Angeles, LBC=Long Beach, LVG=Las Vegas, MIA=Miami, MIN=Minneapolis, NOR=New Orleans, NY=New York City, OKC= Oklahoma City, ORA=Orange County, PHI=Philadelphia, PHX=Phoenix, POR=Portland, SDG=San Diego, SEA=Seattle, SFO=San Francisco, TRP=Tripler Army Medical Center
YRMO	[Char, 6]	Year/ Month of patient's visit	YYYYMM
ID	[Char, 2]	patient or isolate number	01, 02, 03, ... 30 or higher
B_LAC	[Char, 1]	beta-lactamase test	1=positive, 2=negative
PEN	[Num, 6]	penicillin MIC	0.0008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0; 32.0; 64.0
TETRACY	[Num, 6]	tetracycline MIC	0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0; 32.0; 64.0
SPCTINO	[Char, 1]	spectinomycin sensitivity	1=sensitive; 2=resistant
CFX	[Num, 6]	cefixime MIC	0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0
CRO	[Num, 6]	ceftriaxone MIC	0.008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0
CIPRO	[Num, 6]	ciprofloxacin MIC	0.001; 0.002; 0.004; 0.008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0
CPD	[Num, 6]	cefpodoxime MIC	0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0
AZI	[Num, 6]	azithromycin MIC	0.008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0
DATETEST	[Date, 10]	date isolate tested	MM/DD/YYYY
CONTROL	[Char, 1]	Control ID	A, B, C, D

## Appendix 1 (Continued)

### GISP Data Elements

#### Control Strain Susceptibility Testing (Form 3 or CDC 73.60C)

Variable Name	Type/Length	Description	Values
LAB	[Char, 3]	Regional laboratory	EMO=Atlanta regional lab UAB=Birmingham regional lab CLV=Cleveland regional lab UWA=Seattle regional lab
CONTROL	[Char, 1]	Control ID	A, B, C, D
STRAIN	[Char, 9]	strain number	F-18 F-28 SPL-4 P681E CDC 10328 CDC 10329 SPJ-15
B_LAC	[Char, 1]	beta-lactamase test	1=positive, 2=negative
PEN	[Num, 6]	penicillin MIC	0.0008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0; 32.0; 64.0
TETRACY	[Num, 6]	tetracycline MIC	0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0; 32.0; 64.0
SPCTINO	[Char, 1]	spectinomycin sensitivity	1=sensitive; 2=resistant
CFX	[Num, 6]	cefixime MIC	0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0
CRO	[Num, 6]	ceftriaxone MIC	0.008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0
CIPRO	[Num, 6]	ciprofloxacin MIC	0.001; 0.002; 0.004; 0.008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0
CPD	[Num, 6]	cefpodoxime MIC	0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0
AZI	[Num, 6]	azithromycin MIC	0.008; 0.015; 0.03; 0.06; 0.125; 0.25; 0.5; 1.0; 2.0; 4.0; 8.0; 16.0
DATETEST	[Date, 10]	date of isolate testing	MM/DD/YYYY

## Appendix 2

### $\beta$ -lactamase Testing

$\beta$ -lactamase may be detected with a chromogenic cephalosporin test, the Nitrocefin test. Nitrocefin may be obtained from Calbiochem, telephone: 1-800-854-3417, catalog # 484400 in 1 mg or 10 mg quantities.

Methods for detection of  $\beta$ -lactamase may be obtained by selecting “insert” under Technical Resources in the upper left side of the window at

[http://www.calbiochem.com/Products/ProductDetail\\_CBCB.asp?catNO=484400](http://www.calbiochem.com/Products/ProductDetail_CBCB.asp?catNO=484400).

The following is an extract of that pdf document.

#### **Preparing a Nitrocefin (500 mg/L) solution**

- Dissolve 1 mg Nitrocefin in 100  $\mu$ l dimethylsulfoxide (DMSO) and vortex. Add 1.9 ml phosphate buffer (100mM, pH 7.0) to produce 2 ml of the rehydrated powder.
- This yields a working Nitrocefin solution of 500 mg/L (approx. 1 mM), which is suitable for most applications.
- Nitrocefin, particularly in solution, is very sensitive to light. PROTECT FROM LIGHT.
- The stock solution may be stored at  $-20^{\circ}\text{C}$  for up to two weeks.

#### **Techniques for the rapid detection of $\beta$ -lactamase using Nitrocefin**

Direct plate method: Add one drop of the Nitrocefin working solution on to the surface of the colony. If the isolate is a high  $\beta$ -lactamase producer then the colony and the surrounding area will turn red quickly.

Additional methods (a slide method, a broth method, and a paper disc spot method) are also provided in this document.

$\beta$ -lactamase-positive and -negative control strains should be tested with each testing of unknown isolates.

Please note that DMSO is a hazardous chemical; a Material Safety Data Sheet may be obtained at <http://www.calbiochem.com/docs/MSDS/317275-000.pdf>.

## Appendix 3

### Methods for Antimicrobial Susceptibility Testing

#### Antimicrobial Agents and Range of dilutions ( $\mu\text{g/ml}$ ):

<b>Standard panel:</b>	Penicillin G: 0.008 to 64.0
	Tetracycline: 0.06 to 64.0
	Spectinomycin: 128.0
	Cefixime: 0.015 to 2.0
	Ceftriaxone: 0.008 to 2.0
	Ciprofloxacin: 0.001 to 16.0
	Azithromycin: 0.008 to 16.0
	Cefpodoxime: 0.015 to 8.0

#### Retest criteria:

If the MICs of strains are not determined at the highest concentration of agent tested, the MIC should be retested for susceptibility to a higher range of two-fold dilutions. An endpoint must be determined. For specific repeat testing criteria, see page 11.

#### Preparation of Antibiotic-Containing Media

Difco GC medium base (Becton Dickinson, Cockeysville, MD) supplemented with 1% IsoVitaleX (or an equivalent supplement) is used.

1. Prepare the required volume of GC base medium in single strength according to the manufacturer's directions.
2. Autoclave the medium at 121 C for 15 min. Cool to 50 C in a waterbath.
3. Reconstitute the dehydrated IsoVitaleX with the provided diluent according to the manufacturer's directions.
4. Add 10 ml of supplement per liter of base medium, i.e., 1% (v/v); mix thoroughly. This medium is GCS medium.
5. Dispense the required volume of medium into individual containers for the addition of antimicrobial solutions. Maintain media at 50 C in a waterbath.
6. Prepare the working solutions and dilutions of antimicrobial agents from the stock solutions or standard powder.

**Note:** *It is important that no longer than 1-hour elapse between the time that the stock solution is thawed, the dilutions are prepared and added to the base medium and the plates are poured.*

7. Add the required volumes of the prepared working solutions and dilutions of the antimicrobial agents to the respective bottles of GCS medium, mix thoroughly and dispense into *clearly labeled* plates. Thorough mixing of the antibiotics in the medium can be accomplished by swirling the contents three times in a clockwise and counterclockwise motion followed by inverting the bottle three times, minimizing bubble formation.
8. Allow the plates to cool. *Invert the plates and store them in sealed plastic bags at 4 C to 8 C for no longer than two weeks prior to use.*

### **Agar-Dilution Susceptibility Test Procedure**

1. Grow pure cultures of isolates to be tested on chocolate agar at 35 C to 36.5 C in a CO<sub>2</sub>-enriched (5%) atmosphere for 16 to 18 h. Use pure cultures on chocolate agar to prepare the inoculum. *Do not use the first subculture from a frozen culture; subculture these isolates again before using to prepare the inoculum. Do not use isolates grown on antibiotic-containing media to prepare the inoculum.* The complete set of control strains provided by the CDC should be included in each run. If two or more sets of plates (prepared in the same batch) are being inoculated on the same day, it is not necessary to inoculate the complete set of control strains on each set of plates. Two or three control strains may be inoculated on each set of plates, but all control strains should be included in each day's test runs.
2. Use a cotton applicator or a bacteriologic loop to suspend isolated colonies (or cells from less dense areas of growth on the plate) in approximately 2 ml of Mueller-Hinton (MH) broth. (The exact volume of broth required will depend on the method for measuring the turbidity of the suspension. If a spectrophotometer is used, the volume of broth must be sufficient to completely cover the light path and will vary according to the type of spectrophotometer).
3. Adjust the density of the suspension to contain 10<sup>8</sup> colony forming units (CFU)/ml by comparison with a 0.5 McFarland BaSO<sub>4</sub> turbidity standard. (If a spectrophotometer is used to measure the optical density of the suspensions, set the wavelength at 450 nm. Adjust the turbidity to approximately 0.15. It may be necessary to dilute this suspension further than indicated in step #4. Determine the viable count for the suspension and either adjust the initial optical density to which the suspension is prepared or the dilution to give a final viable count of 10<sup>7</sup> CFU/ml as indicated in step #4.)
4. Dilute this suspension 1:10 in MH (or equivalent) broth to give 10<sup>7</sup> CFU/ml.
5. Dispense an equal volume of each suspension into wells of a replicating device, e.g., Steer's or Cathra replicators. These replicating devices deliver 0.001 - 0.005 ml of the bacterial suspension to the surface of the medium, i.e., 10<sup>4</sup> CFU.
6. Inoculate each plate of the set of antibiotic containing media plus a plate of chocolate agar or GCS medium (as a control to determine that all isolates grew). You may also wish to inoculate a GCS plate between each set of antibiotic-containing medium to ensure against carry-over of antimicrobial agents from one medium to another; these plates also allow for monitoring for contamination of the inocula during the inoculation process.

**Note.** *The time elapsing between the preparation of the strain suspensions and inoculation of the plates should not exceed 1 h.*

7. Allow the inoculated plates to air-dry at room temperature for approximately 15 min. Invert the plates and incubate at 35 C to 36.5 C in a CO<sub>2</sub>-enriched (5%) atmosphere for 24 h.
8. Examine the plates for growth. Use a separate sheet to record the results for each antibiotic tested and record the growth for each isolate on each antibiotic concentration tested. Record the growth as good (+), poor ( $\pm$ ), or no growth (-). By using this scheme, the results can be reviewed at a later date for transcription errors and, when isolates grow on the highest concentration tested, the degree of growth will indicate whether the isolate is growing strongly or is partially inhibited.

## Appendix 4

### Agar Dilution Susceptibility Testing - CDC Reference Strains of *Neisseria gonorrhoeae*

Strain #	Resistance phenotype <sup>a</sup>	Range [Modal] MIC (µg/ml)								
		β-lac	Pen	Tet	Spc	Cro	Cfx	Cip	Azi	Ery <sup>c</sup>
F-18 <sup>b</sup>	Susc	-	0.25-1.0 [1.0]	0.25-1.0 [1.0]	#128.0 [#128.0]	0.004-0.015 [0.015]	0.004-0.03 [0.03]	0.001-0.008 [0.004]	0.125-0.5 [0.25-0.5]	1.0-2.0 [2.0]
F-28	Susc, SpcR	-	0.015-0.06 [0.03]	0.125-0.5 [0.25]	>128.0 [>128.0]	0.0005-0.002 [0.001]	0.001-0.008 [0.002]	0.001-0.004 [0.002]	0.03-0.125 [0.06]	0.125 [0.125]
P681E	PP/TR	+	2.0-≧64.0 [8.0]	8.0-32.0 [16.0]	#128.0 [#128.0]	0.002-0.008 [0.004]	0.008-0.03 [0.015]	0.002-0.008 [0.004]	0.003-0.125 [0.06]	0.06-0.125 [0.125]
CDC 10328	PPNG, CipI	+	4.0-≧32.0 [ND]	0.25-1.0 [0.5-1.0]	#128.0 [#128.0]	0.002-0.015 [0.004]	0.004-0.03 [0.008-0.015]	0.125-0.5 [0.25]	0.015-0.125 [0.03]	0.5
CDC 10329	PPNG, TetR, CipR	+	16.0-≧64.0 [ND]	2.0-4.0 [2.0-4.0]	#128.0 [#128.0]	0.004-0.03 [0.008-0.015]	0.008-0.06 [0.015]	1.0-2.0 [1.0]	0.125-0.5 [0.25-0.5]	1.0
SPJ-15	Susc, Azi C	-	0.5-1.0 [0.5]	1.0-4.0 [1.0-2.0]	#128.0 [#128.0]	0.004-0.015 [0.008]	0.008-0.06 [0.03]	0.004-0.008 [0.004]	1.0-8.0 [2.0-4.0]	4.0-8.0 [8.0]
SPL-4	CMRNG, CipR, Cfx DS	-	4.0-16.0 [8.0]	2.0-8.0 [4.0]	#128.0 [#128.0]	0.03-0.25 [0.125]	0.25-0.5 [0.5]	8.0-32.0 [8.0-16.0]	0.125-0.5 [0.25]	ND

Abbreviations. β-lac, β-lactamase; Pen, penicillin; Tet, tetracycline; Spc, spectinomycin; Cro, ceftriaxone; Cfx, cefixime; Cip, ciprofloxacin; Azi, azithromycin; Susc, susceptible to penicillin and tetracycline (MICs <2.0 µg/ml); SpcR, spectinomycin-resistant (MIC >128.0 µg/ml); PP/TR, β-lactamase-positive strains with MICs ≥16.0 µg/ml of tetracycline; PPNG, penicillinase (β-lactamase)-producing *N. gonorrhoeae*; TetR, MIC <2.0 µg/ml of penicillin and MIC ≥2.0 µg/ml of tetracycline; CipI, strain with MIC of 0.125-0.5 µg/ml of ciprofloxacin; CipR, strain with MIC of ≥1.0 µg/ml of ciprofloxacin; Azi C, isolates exhibiting critical MICs (MIC ≥1.0 µg/ml) of azithromycin; CMRNG, β-lactamase-negative and MIC >2.0 µg/ml of penicillin and MIC ≥2.0 to 8.0 µg/ml of tetracycline; Cfx DS, isolates exhibiting decreased susceptibility (MIC ≥0.5 µg/ml) to cefixime; ND, Not Determined.

<sup>a</sup>Resistance phenotypes are composed of resistance phenotypes for penicillin and tetracycline according to GISP definitions supplemented with specific designations for spectinomycin, ciprofloxacin, azithromycin, and cefixime.

<sup>b</sup>ATCC49226, NCCLS-recommended quality control strain for *N. gonorrhoeae*; MIC ranges are those published by NCCLS.

<sup>c</sup>Erythromycin range and modal values were calculated from fewer results than range and modal values for the other antimicrobial agents.

## Summary of GISP Timelines for Project Participants

### Sentinel Sites:

1. **Demographic and clinical data** (i.e., Form 1) - Due monthly to CDC, no more than 4 weeks after the end of the month in which the corresponding isolates were collected.
2. **Isolates** - Due monthly to assigned Regional Laboratory, shipping out on Monday or Tuesday of the week immediately following completion of isolate collection but no later than the first Monday of the following month.
3. **CSPS STD grant application reporting** - Due annually, when CSPS grant applications are due in late summer or early fall.

### Regional Laboratory:

1. **Testing of isolates** - Should be completed within one month of receipt of isolates.
2. **Susceptibility test data** (i.e., Form 2) - Due monthly to CDC and to Sentinel Sites, within one week of completion of testing.
3. **Control strain susceptibility test data** (i.e., Form 3) - Due monthly to CDC, within one week of completion of testing (together with the Sentinel Site Form 2 susceptibility data obtained from the same run).
4. **Notification of Alert Value Isolates** - Reporting of the identification of Alert Value Isolates to CDC should take place within one working day of when the test results are read. Confirmatory testing should be done within a month of first test.
5. **CSPS grant application reporting** - Due annually, when CSPS grant applications are due in late summer or early fall.

### CDC:

1. **Final date for receiving corrections or updates to previous year's GISP data from Sentinel Sites and Regional Laboratories** - Mid-March
2. **Electronic GISP data files for Sentinel Sites** - Available by August upon request to GISP Data Manager.
3. **Publish annual GISP Report** - By fall of the year following the year of isolate collection.
4. **Notification of Alert Value Isolates** - Will report the identification of Alert Value Isolates to the Sentinel Sites from which they were submitted and to the pertinent local and/or state STD Program within one working day of the information being reported to CDC by the Regional Laboratory.

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