

Gonococcal Isolate Surveillance Project (GISP)



Coding Guide

GONOCOCCAL ISOLATE SURVEILLANCE PROJECT

Instructions for completing Form 1 - Demographic/Clinical Data

ITEMS:

1. **Sentinel Site (3 letter code):** Enter the appropriate 3 letter code.

Albuquerque	ALB	Las Vegas	LVG
Atlanta	ATL	Los Angeles	LAX
Birmingham	BHM	Minneapolis	MIN
Boston	BOS	New Orleans	NOR
Buffalo	BUF	New York City	NYC
Chicago	CHI	Orange County	ORA
Cleveland	CLE	Philadelphia	PHI
Columbus	COL	Phoenix	PHX
Dallas	DAL	Pontiac	PON
Greensboro	GRB	Portland	POR
Honolulu	HON	San Diego	SDG
Indianapolis	IND	San Francisco	SFO
Kansas City	KCY	Seattle	SEA
		Tripler	TRP

2. **Specimens collected during (Year/Month):** Enter all four digits of the current calendar year followed by the two digit code indicating the month (01 for January, 02 for February, etc). Example: The Year/Month code for March, 2014 would be 201403.
3. **Patient Number:** Patient number based on sequential identification of the first 25 male patients with presumptive or confirmed diagnosis of gonorrhea each month. The data entry program requires an entry in this field. You must enter the two digit number that is assigned to the patient's isolate at the local lab, including leading zeros (i.e. "01" instead of "1").
4. **Clinic:** For Sentinel Sites using more than one clinic to collect the GISP sample, the clinic code should be entered here. Each clinic is assigned a single-digit code by the Sentinel Site; codes and the corresponding clinic names should be given to the GISP data manager. Any changes in participating clinics should be communicated to the GISP data manager.

5. **Sex:** Although the GISP protocol restricts isolate procurement to male patients only, errors do occur. If an isolate is unintentionally submitted to the lab from a female patient, identifying the sex of the patient on Form 1 will prevent this patient from being coded as a "case" in the GISP database at the coordinating center. Although the data entry program will accept an entry of "2" for "female", you will be asked to confirm your selection. If the patient has male genitalia, please code as male.

1= male
2= female
9= unknown sex

Note: Specifying that patients with male genitalia should be classified as "1" (even if transgendered) was made explicit in 2014.

6. **Ethnicity:** This question pertains to patients of Hispanic origin and/or native Spanish speakers. If this information is solicited for the patient's record, please code accordingly. Do not assume a patient's ethnicity based on surname alone, as people can change their names, be adopted, etc. Use only self-reported ethnic status. Furthermore, *note that race and ethnicity are not mutually exclusive variables.* Individuals who indicate their ethnicity as "Hispanic" are not necessarily "white". If the information is unavailable, please code this item "9" to indicate "unknown". If the patient is described as "Hispanic" with no accompanying race data, please code "1" for ethnicity.

1= Hispanic
2= non-Hispanic
9= unknown ethnicity

7. **Race:** It is important to be as precise as possible with regard to demographic data as it may be used as an indicator of, or proxy for, other variables affecting morbidity outcomes such as socioeconomic status. We realize that data on race may not be collected at each site; however, where the information is available, please use the following guidelines in coding these data.

Self-reported race status is considered to be the most valid. If race is not self-reported in the clinic record, but is noted by the clinician, this information may be used. If there is a conflict between the two, e.g., the patient self-reports that racial status is "white", but the clinician describes patient as "black", use the self-reported status.

You should respond "yes" for all race categories that apply.

American Indian/ Alaskan Native

- 1= yes
- 2= no
- 9= unknown

Asian

- 1= yes
- 2= no
- 9= unknown

Black or African-American

- 1= yes
- 2= no
- 9= unknown

Native Hawaiian/ Pacific Islander

- 1= yes
- 2= no
- 9= unknown

White

- 1= yes
- 2= no
- 9= unknown

Other

- 1= yes
- 2= no
- 9= unknown

8. **Date of Clinic Visit (mm/dd/yyyy):** Enter the month, day, and year of the clinic visit at which the positive gonorrhea culture was obtained. If the day is unknown, enter "01" for day. The year and month should correspond to the year and month entered for item 2 above.
9. **Age:** Enter patient's age in years. Code unknown age or missing data as "99".
10. **Sexual Orientation:** Sex of the patient's sexual partners within the past 3 months. In clinics where sex of sex partner is not directly ascertained from the patient, code "9" for "unknown". **Do not code data on sexual orientation "heterosexual" by default.**
 - 1= women only (heterosexual)
 - 2= men only (homosexual)
 - 3= women and men (bisexual)
 - 9= unknown

Note: Prior to 2013, this variable was defined as "sexual orientation" and responses were categorized as heterosexual

(1), homosexual (2), and bisexual (3).

11. **Symptoms:** This question pertains to the symptoms of **urethral gonorrhea only** (such as discharge and dysuria [pain with urination]). If there is no data in the record regarding the presence OR absence of urethral gonorrhea symptoms, code this field "9" indicating "unknown symptomatology".

1= discharge and/or dysuria
2= no discharge and no dysuria
9= unknown symptomatology

12. **Previous History of Gonorrhea (ever):** Please note any previous documented or self-reported history of gonorrhea in patient's lifetime. If there is no information concerning history in the record, code "9" to indicate "unknown".

1= yes
2= no
9= unknown

13. **Number of Previous Episodes in Past Year:** Enter the **number** of previous episodes of gonorrhea **documented** in the patient's record within the **past 12 months**.

Please code:

0= no documented previous episodes in the past 12 months (includes patients for whom this is the initial clinic visit)

99= unknown (patient record not available or clinic staff unable to collect this information due to record-keeping system)

14. **HIV Status:** Enter patient's HIV status as known at the time of the clinic visit for gonorrhoea. Code "1" for "positive" if the patient's medical record documents a positive HIV test or if the patient self-reports as HIV-positive. This can include rapid tests for which results are available on the day of the clinic visit. Code "2" for "negative" if the patient's medical record documents a negative HIV test within the previous 3 months. If the available information does not allow you to code "1" or "2," then code "9" for "unknown."

1= positive
2= negative
3= indeterminate
9= unknown

15. **Travel History (previous 60 days):** Code "1" for "yes" if the patient traveled outside of the United States (50 U.S. states) during the previous 60 days. Code "2" for "no" if the patient did not travel internationally during the previous 60 days. If travel information is not available, code "9" for "unknown."

1= yes
2= no
9= unknown

Note: From November 2005-December 2013, this variable was defined as travel outside of the state where the sentinel site is located, in the previous 60 days. Prior to November 2005, this variable was defined as travel to Hawaii or outside of the United States in the previous 60 days.

16. **Sex Work Exposure (previous 12 months):** If the patient exchanged drugs or money for sex (or exchanged sex for drugs or money) during the previous 12 months, code "1" for "yes." If the patient did not exchange drugs or money for sex (or sex for drugs or money), code "2" for "no." If it is unknown whether the patient had sex work exposure, code "9" for "unknown." **Do not code "2" for "no" by default.**

1= yes
2= no
9= unknown

Note: Prior to 2014, the time period for this variable was the previous 60 days. In 2014, the time period was changed to 12 months to align with other surveillance data systems.

17. **Previous Antibiotic Use (previous 60 days):** Code "1" for "yes" if the patient took antibiotics for any reason during the previous 60 days. This should only include systemic oral or injectable antibiotics, and should not include antibiotic ointments or eye drops. Code "2" for "no" if the patient did not take antibiotics for any reason during the previous 60 days. If it is unknown whether or not the patient took antibiotics, code "9" for "unknown." **Do not code "2" for "no" by default.**

1= yes
2= no
9= unknown

Note: Starting in 2014, language stating that "This should only include systemic antibiotics, taken orally or by injection, and should not include antibiotic ointments or eye drops," was added.

18. **Injection Drug Use (previous 12 months):** Code "1" for "yes" if the patient reported using recreational injection drugs during the previous 12 months. Code "2" for "no" if the patient reported not doing recreational injection drugs during the previous 60 days. If it is unknown whether or not the patient used recreational injection drugs, code "9" for "unknown." **Do not code "2" for "no" by default.**

1= yes
2= no
9= unknown

Note: Prior to 2014, the time period for this variable was the previous 60 days. In 2014, the time period was changed to 12 months to harmonize with other surveillance data systems.

19. **Noninjection Drug Use (previous 12 months):** Code "1" for yes if the patient reported using recreational non-injection drugs during the previous 12 months. Examples: ecstasy, crack, cocaine, marijuana, methamphetamines, poppers. (But excluding alcohol, medications for erectile dysfunction, and steroids.) Code "2" for "no" if the patient reported not doing recreational non-injection drugs during the previous 60 days. If it is unknown whether or not the patient used recreational non-injection drugs, code "9" for "unknown." **Do not code "2" for "no" by default.**

1= yes
2= no
9= unknown

Note: Prior to 2014, the time period for this variable was the previous 60 days. In 2014, the time period was changed to 12 months to align with other surveillance data systems. In 2014, the statement that this variable "excludes alcohol, medications for erectile dysfunction, and steroids," was added.

20. **Treatment One (Primary treatment of gonorrhea):** Indicate the primary antimicrobial prescribed to treat the case of gonorrhea. Please use the two-digit treatment codes below. If entering the code "88" for "other", include the **name** of the drug in the space provided. If no treatment **for gonorrhea** was given, code "00". You must enter both digits of the treatment code, including leading zeros. Please note that "01" and "02" are not valid codes.

00= no treatment given
03= spectinomycin (Trobicin) 2 g
04= ceftriaxone (Rocephin) 250 mg
05= ceftriaxone (Rocephin) 125 mg
06= ciprofloxacin (Cipro) 500 mg
07= ceftiofloxacin (Mefoxin) 2 g
12= cefixime (Suprax) 400 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
27= gemifloxacin 320 mg
28= gentamicin 240 mg (or weight-based dosage)
88= other primary treatment and dosage for gonorrhea (please indicate name and dosage below)
99= therapy data unknown/ missing

Note: gemifloxacin and gentamicin were added in 2014.

25. **Other Treatment One:** If code "88" ("other") was entered for **Treatment One**, write in the name and dosage of the primary antimicrobial therapy for gonorrhea and dosage that was administered.
26. **Treatment Two (Second antibiotic used for treatment of gonorrhea and (if appropriate) treatment of chlamydia):** In many cases, two antibiotics may be prescribed for patients diagnosed with gonorrhea. Dual therapy (treatment with a cephalosporin antibiotic and either azithromycin or doxycycline) has been recommended for treatment of gonorrhea since 2010. In addition, patients that are diagnosed with and

treated for gonorrhea are often treated for chlamydia at the same time. The recommended therapies for chlamydia are doxycycline and azithromycin. Seven-day courses of erythromycin, amoxicillin, levofloxacin, and ofloxacin are alternatives for selected patients.

If dual therapy was administered, indicate the second antimicrobial used. If therapy for chlamydia alone was given, indicate this therapy. Please use the treatment codes below. Code "88" for other **only** if the dual therapy did not include any of the listed treatment options. You must enter a two-digit code in this field, including leading zeros.

00= no secondary treatment given
01= ampicillin/amoxicillin
09= doxycycline (Vibramycin)/tetracycline
10= erythromycin
11= azithromycin (Zithromax) 1 g
15= ofloxacin
21= azithromycin (Zithromax) 2 g
22= levofloxacin
88= other
99= therapy data unknown/missing

Previously collected variables

Monthly Clinic Totals for Gonorrhea: Not collected after 2013.

The total numbers of gonorrhea episodes diagnosed during the entire month for male and for female patients at the site, and the sum of these two numbers. Multiple episodes in one patient in a given month were to be counted individually. Sites with more than one clinic submitting isolates to GISP were to enter sum of totals for all contributing clinics.

Date of Birth (mm/dd/yyyy): Not collected after 2013.

If year of birth was known, but month and/or day was unknown, "01" was entered for month and/or day.

Reason for Visit: Not collected after 2013.

This variable was coded "volunteer" when the patient has requested treatment of his own volition. Patient were coded as "contact" if they had requested treatment because he is a sexual contact of a patient with gonorrhea, or because he had been informed of a potential exposure to gonorrhea by a health department/DIS. Patients who sought treatment because of sexual contacts having other diagnosed STDs or were referred by a private physician were coded as "other".

1= volunteer

2= contact to gonorrhoea
3= test of cure
8= other
9= unknown

Zipcode: Not collected after 2013.

00000= homeless
99999= unknown zip code

GONOCOCCAL ISOLATE SURVEILLANCE PROJECT

Instructions for completing Form 2 - Antimicrobial Susceptibility Testing

ITEMS:

1. **Sentinel Site (3 letter code):** Enter the appropriate 3 letter code.

Albuquerque	ALB	Las Vegas	LVG
Atlanta	ATL	Los Angeles	LAX
Birmingham	BHM	Minneapolis	MIN
Boston	BOS	New Orleans	NOR
Buffalo	BUF	New York City	NYC
Chicago	CHI	Orange County	ORA
Cleveland	CLE	Phoenix	PHX
Columbus	COL	Pontiac	PON
Dallas	DAL	Portland	POR
Greensboro	GRB	San Diego	SDG
Honolulu	HON	San Francisco	SFO
Indianapolis	IND	Seattle	SEA
Kansas City	KCY	Tripler	TRP

2. **Specimens collected during (Year/Month):** Enter all four digits of the current calendar year followed by the two digit code indicating the month (01 for January, 02 for February, etc). Example: The Year/Month code for March, 2004 would be 200403.
3. **Isolate Number:** Sequential identifier corresponding to the patient number in the demographic/clinical data. You must enter a two digit number, including leading zeros (i.e. "01" instead of "1").

ANTIMICROBIAL SUSCEPTIBILITY TESTING: Please use only the dilutions indicated for each drug. Currently recommended testing range is bolded.

4. ***β-Lac***: (β-lactamase test)

1=positive
2=negative

5. ***Pen***: (Penicillin MIC)

Valid dilutions: 0.008; 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

6. ***Tet***: (Tetracycline MIC)

Valid dilutions: 0.06; 0.125; **0.25; 0.5; 1.0; 2.0; 4.0; 8.0;**
16.0; 32.0; 64.0

7. ***Spc***: (Spectinomycin sensitivity)

1= sensitive (MIC < 128 µg/ml)
2= resistant (MIC ≥ 128 µg/ml)

8. ***Cfx***: (Cefixime MIC)

Valid dilutions: 0.002; 0.004; **0.015; 0.03; 0.06; 0.125;**
0.25; 0.5; 1.0; 2.0

9. ***Cro***: (Ceftriaxone MIC)

Valid dilutions: 0.001; 0.002; 0.004; **0.008; 0.015; 0.03;**
0.06; 0.125; 0.25; 0.5; 1.0; 2.0

10. ***Cip***: (Ciprofloxacin MIC)

Valid dilutions: 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

11. ***Azi***: (Azithromycin MIC)

Valid dilutions: 0.008; 0.015; **0.03; 0.06; 0.125; 0.25; 0.5;**
1.0; 2.0; 4.0; 8.0; 16.0

12. ***Date Tested (mm/dd/yyyy)***: Enter month, day, and year of isolate testing.

13. **Control ID (A, B, C, or D):** Enter control ID for control strains that are tested with the batch of sentinel site strains. This must correlate with information entered on Form 3 Control Strain Susceptibility Testing.

GONOCOCCAL ISOLATE SURVEILLANCE PROJECT

Instructions for completing Form 3 - Control Strain Susceptibility Testing
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ITEMS:

1. **Regional Laboratory (3 letter code):** Enter the appropriate 3 letter code.

Atlanta, Emory University	EMO
Birmingham, University of Alabama	UAB
Austin, Texas Department of State Health Services	AUS
Seattle, University of Washington	UWA
Baltimore, Johns Hopkins University	JHU

2. **Control ID:** Distinguishes different test runs for group of control strains by date tested. No data entry required.
3. **Strain Number:** Identifier for specific control strains.

ANTIMICROBIAL SUSCEPTIBILITY TESTING: Enter as for **Form 2**. For complete instructions, including valid value ranges for each drug, see instructions for **Form 2** in this handbook.

4. **Date tested (mm/dd/yyyy):** Enter the month, day, and year on which antimicrobial susceptibility testing for the isolate was completed.