

GONOCOCCAL ISOLATE SURVEILLANCE PROJECT
(GISP)

Coding Guide and Epi Info Program Handbook

January 2004

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. You must enter data in this field. To facilitate data entry, **the Epi Info program will repeat the entry in this field for all subsequent records until you type in a new code.**

Albuquerque	ALB	Los Angeles	LAX
Atlanta	ATL	Miami	MIA
Baltimore	BAL	Minneapolis	MIN
Birmingham	BHM	New Orleans	NOR
Chicago	CHI	Oklahoma City	OKC
Cincinnati	CIN	Orange County	ORA
Cleveland	CLE	Philadelphia	PHI
Dallas	DAL	Phoenix	PHX
Denver	DEN	Portland	POR
Detroit	DTR	San Diego	SDG
Greensboro	GRB	San Francisco	SFO
Honolulu	HON	Seattle	SEA
Las Vegas	LVG	St. Louis	STL
Long Beach	LBC	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. You must enter data in this field. To facilitate data entry, **the Epi Info program will repeat the entry in this field for all subsequent records until you type in a new value.**
3. **Monthly Clinic Totals for Gonorrhoea:** Enter the year (all four digits) and month (two-digit numeric code) to which the clinic totals correspond. Clinic totals may be submitted for the current or previous month. Enter the total numbers of gonorrhoea 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 are to be counted individually. For sites with more than one clinic submitting isolates to GISP, please enter sum of

totals for all contributing clinics.

4. **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").
5. **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.
6. **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 gender 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 receive a warning flag which asks "Are you sure this is a female (yes/no)?". If the patient is a female, press "Y" and continue entering data. If you wish to correct your entry, i.e., it is a male patient, type "N", and enter "1" for "male". You must enter a code in this field.

1= male
2= female
9= unknown gender

7. **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. You must enter a code in this field.

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

8. **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

Asian

- 1= yes
- 2= no

Black

- 1= yes
- 2= no

Native Hawaiian/ Pacific Islander

- 1= yes
- 2= no

White

- 1= yes
- 2= no

Other

- 1= yes
- 2= no

9. **Date of Clinic Visit (mm/dd/yyyy):** Enter the month, day, and year of the clinic visit at which the positive gonorrhoea 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. You must enter data in this field. (Backslashes are entered automatically by the Epi Info program, therefore you do not need to type these in).

10. **Date of Birth (mm/dd/yyyy)**: Enter the month, day, and year of the patient's birth. If year of birth is known, but month and/or day is unknown, enter "01" for month and/or day (i.e. for a patient born on an unknown month and day in 1973, enter "01/01/1973"). **If date of birth is unknown, enter "99/99/9999" on the data entry form and leave this field blank in the Epi Info data entry program.** (Epi Info will not accept a code for a missing date value). The data entry program is designed to "flag" entries corresponding to very high or low age values to prevent errors due to miskeying of data. If you receive an on-screen warning, verify your entry and answer the prompt accordingly.

11. **Age**: Enter patient's age in years **only if Date of Birth is unknown**. Code unknown age or "missing data" as "99". The Epi Info program will calculate Age from Date of Clinic Visit and Date of Birth, provided that neither of these is missing. If Date of Birth is missing, you must enter data in this field. The data entry program is designed to "flag" entries for very high or low age values to prevent errors due to miskeying of data. If you receive an on-screen warning, verify your entry and answer the prompt accordingly.

12. **Sexual Orientation**: In clinics where sexual orientation is not directly ascertained from the patient, code "9" for "unknown". **Do not code data on sexual orientation "heterosexual" by default.** You must enter a code in this field.

1= heterosexual
2= homosexual
3= bisexual
9= unknown

13. **Symptoms**: This question pertains to the symptoms of **gonorrhoea only**. If there is no data in the record regarding the presence OR absence of gonorrhoea symptoms, code this field "9" indicating "unknown symptomatology". You must enter a code in this field.

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

14. **Reason for Visit**: This variable should be coded "volunteer" when the patient has requested treatment of his own volition. If a patient has requested treatment because he is a sexual contact of a patient with gonorrhoea, or because he has been informed of a potential exposure to gonorrhoea by a health

department/DIS, please code "contact". Patients who seek treatment because of sexual contacts having other diagnosed STDs should be coded "other". Patients referred by a private physician should be coded "other".

When multiple specimens are obtained at different visits from an individual patient in a given month, be sure to distinguish between reason for the initial visit, and reason for subsequent visits. For example, an individual patient could have a "volunteer" visit, "test of cure" visit and a *repeat* or second "volunteer" visit in a given month. Please code "9" for "unknown" reason for visit. You must enter a code in this field.

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

15. ***Previous History of Gonorrhoea (ever)***: Please note any previous documented or self-reported history of gonorrhoea in patient's lifetime. If there is no information concerning history in the record, code "9" to indicate "unknown". You must enter a code in this field.

1= yes
2= no
9= unknown

16. ***Number of Previous Episodes in Past Year***: Enter the **number** of previous episodes of gonorrhoea **documented** in the patient's record within the **past 12 months**. **You must enter data in this field.**

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)

17. **Zipcode:** Enter the patient's residential zip code. You must enter data in this field.

Please code:

00000= homeless

99999= unknown zip code

18. **HIV Status:** Enter patient's HIV status as known at the time of the clinic visit for gonorrhea. Code "1" for "positive" if the patient's medical record documents a positive HIV test or if the patient self-reports as HIV-positive. 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." **Do not code "2" for "negative" by default.**

1= positive

2= negative

9= unknown

19. **Travel History (previous 60 days):** Code "1" for "yes" if the patient traveled outside the state where the Sentinel Site is located during the previous 60 days. Code "2" for "no" if the patient did not travel outside the state where the Sentinel Site is located during the previous 60 days. If travel information is not available, code "9" for "unknown."

1= yes

2= no

9= unknown

20. **Sex Work Exposure (previous 60 days):** If the patient exchanged drugs or money for sex (or exchanged sex for drugs or money) during the previous 60 days, 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

21. **Previous Antibiotic Use (previous 60 days):** Code "1" for "yes" if the patient took antibiotics for any reason during the previous 60 days. 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

22. **Injection Drug Use (previous 60 days):** Code "1" for "yes" if the patient reported using recreational injection drugs during the previous 60 days. 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

23. **Noninjection Drug Use (previous 60 days):** Code "1" for yes if the patient reported using recreational non-injection drugs (**excluding alcohol**) during the previous 60 days. 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.** Examples: ecstasy, crack, cocaine, marijuana, methamphetamines, poppers.

1= yes
2= no
9= unknown

24. **Treatment One (Gonorrhea):** Indicate the antimicrobial therapy 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. **Code "88" should be used only for an alternative primary antimicrobial therapy for gonorrhea.** Note that doxycycline/tetracycline, coded "09", and erythromycin, coded "10" are not generally given as primary treatments for gonorrhea, but rather as treatments for potential co-infection with chlamydia (see "Treatment Two" below). 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
 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 primary treatment and dosage for gonorrhea (please indicate name and dosage below)
 99= therapy data unknown/ missing

25. **Other Treatment One:** If code "88" ("other") was entered for **Treatment One**, write in the name and dosage of the alternative primary antimicrobial therapy for gonorrhea and dosage that was administered.

26. **Treatment Two (Chlamydia):** Patients that are diagnosed with and treated for gonorrhea are often presumptively treated for chlamydia at the same time. Some patients later found to have gonorrhea are treated only for chlamydia or NGU on the day of visit. The recommended therapies for chlamydia are doxycycline, tetracycline, and azithromycin. Erythromycin and amoxicillin are alternatives for selected patients. Ofloxacin, in a one-week regimen (**not** the single dose given for gonorrhea), may also be used.

If dual therapy was administered, indicate the antimicrobial therapy used to treat for possible co-infection with chlamydia. 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/tetracycline
 10= erythromycin
 11= azithromycin (Zithromax) 1 g
 15= ofloxacin
 88= other
 99= therapy data unknown/ missing

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. You must enter data in this field. To facilitate data entry, **the Epi Info program will repeat the entry in this field for all subsequent records until you type in a new code.**

Albuquerque	ALB	Los Angeles	LAX
Atlanta	ATL	Miami	MIA
Baltimore	BAL	Minneapolis	MIN
Birmingham	BHM	New Orleans	NOR
Chicago	CHI	Oklahoma City	OKC
Cincinnati	CIN	Orange County	ORA
Cleveland	CLE	Philadelphia	PHI
Dallas	DAL	Phoenix	PHX
Denver	DEN	Portland	POR
Detroit	DTR	San Diego	SDG
Greensboro	GRB	San Francisco	SFO
Honolulu	HON	Seattle	SEA
Las Vegas	LVG	St. Louis	STL
Long Beach	LBC	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, 2002 would be 200203. You must enter data in this field. To facilitate data entry, **the Epi Info program will repeat the entry in this field for all subsequent records until you type in a new value.**
3. **Isolate Number:** Sequential identifier corresponding to the patient number in the demographic/clinical data. The data entry program requires an entry in this field. 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. **No other entries will be accepted! The data entry program will accept only one of the valid dilutions listed below and on the form.**

4. **β -Lac:** (β -lactamase test) Check the appropriate box on the data entry form and enter the numeric code in the data entry program.

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

In order to minimize errors due to miskeying during data entry, the Epi Info program will ask you to confirm the code you entered for **β -Lac** if you enter code "1" for "positive" followed by a penicillin MIC of less than 2.0, or code "2" for "negative" followed by a penicillin MIC of greater than 4.0.

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) Check the appropriate box on the data entry form and enter the numeric code in the data entry program.

1= sensitive (MIC < 128 μ g/ml)
2= resistant (MIC \geq 128 μ g/ml)

As spectinomycin resistant isolates are not frequently seen, the Epi Info program will ask you to confirm your entry if you enter code "2" for "resistant".

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

Valid dilutions: 0.002; 0.004; 0.008; 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. **Ery:** (Erythromycin MIC) ***Discontinued as of 10/2003**

12. **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

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

14. **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.

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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. You must enter data in this field. To facilitate data entry, **the Epi Info program will repeat the entry in this field for all subsequent records until you type in a new code.**

Atlanta, Emory University	EMO
Birmingham, University of Alabama	UAB
Cleveland Clinic Foundation	CLV
Denver Health and Hospitals	DHH
Seattle, University of Washington	UWA

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. No data entry required.

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. You must enter data in this field.