

Gonococcal Isolate Surveillance Project

OMB 0920-0307

Sancta St. Cyr, Project Officer

Attachment 7

Data Coding Guide

Core and Enhanced Clinical/Demographic Data Elements

| Variable Name | Type/Length | Description | Values | Comments |
|----------------------|-------------|---|--|--|
| PATIENT_ID | [Char, 18] | Patient ID | ##### | An eGISP patient identifier should be created which is unique within the jurisdiction, remain consistent across visits and the life cycle of eGISP, and not contain personally identifiable information (PII). |
| eGISP_SPEC_ID | [Char, 18] | eGISP/SURRG ID | e.g., CHICC170107918. | For all isolates collected, sites should assign and maintain an eGISP/SURRG specimen ID for all isolates, constructed using the 3 letter sentinel site code + local PHL accession number (no hyphens or spaces). |
| SPECIMEN_TYPE | [Char, 2] | Anatomic site of specimen collection | U=urethral V=vaginal E=endocervical R=rectal P=pharyngeal NC=not captured | |
| NAAT_GC | [Char, 1] | Nucleic acid amplification test (NAAT) result | 1=positive 2=negative 3=indeterminate/ equivocal 9=unknown | |

| Variable Name | Type/Length | Description | Values | Comments |
|--------------------|-------------|--|---|---|
| POSSIBLE_NM | [Char, 1] | Isolate suspected to be <i>N. meningitidis</i> | 1=isolate may be <i>N. meningitidis</i> 2=isolate has been positively identified as <i>N. gonorrhoeae</i> | A possible <i>N. meningitidis</i> isolate is considered when an isolate has (i) the growth of typical appearing <i>N. gonorrhoeae</i> colonies with typical morphologies (e.g., small, transparent) on a selective medium such as Thayer-Martin at 35o C to 36.5o C in 5% CO2, (ii) a positive oxidase test, (iii) the observation of Gram-negative, oxidase-positive diplococci in stained smears and (iv) a negative NAAT result. If additional testing is performed to confirm the species of the isolate, this information can also be used to make a determination. |
| NmVacc | [Char, 1] | Prior history of meningococcal vaccination | 1= MenACWY vaccine only 2= MenB vaccine only 3= Men ACWY + MenB vaccine 4= Meningococcal/meningitis vaccine, but unknown 5= No meningitis vaccine 9= Unknown | There are several vaccines for meningitis available. The MenACWY vaccines are called Menactra or Menveo. MenB vaccines are called Trumenba and Bexsero. If it is known that a patient has received no meningococcal vaccine, please mark "No meningitis vaccine". Otherwise mark "unknown". |
| CLINIC | [Char, 3] | Sentinel site code | ALB = Albuquerque ANC= Anchorage BAL= Baltimore BHM=Birmingham | |

| Variable Name | Type/Length | Description | Values | Comments |
|---------------|-------------|-------------|-------------------------------------|----------|
| | | | BUF= Buffalo | |
| | | | CAM= Camden | |
| | | | CHI=Chicago | |
| | | | CLE = Cleveland | |
| | | | COL=Columbus | |
| | | | DAL=Dallas | |
| | | | DEN=Denver | |
| | | | FSM =Federated States of Micronesia | |
| | | | GRB=Greensboro | |
| | | | HON=Honolulu | |
| | | | IND=Indianapolis | |
| | | | JAC= Jackson | |
| | | | KCY=Kansas City | |
| | | | LVG=Las Vegas | |
| | | | LA1/LA2=Los Angeles | |
| | | | MIA=Miami | |
| | | | MIL=Milwaukee | |
| | | | MIN=Minneapolis | |
| | | | NOR=New Orleans | |
| | | | NYC= New York City | |

| Variable Name | Type/Length | Description | Values | Comments |
|---------------------|-------------|--------------------------|---|--|
| | | | ORA=Orange County PHI=Philadelphia PHX=Phoenix PON=Pontiac POR=Portland SDG=San Diego SEA= Seattle SFO=San Francisco TRP=Tripler WDC= Washington, DC | |
| CLINID | [Char, 1] | Clinic identifier number | 1, 2, 3...9 | For Sentinel Sites using more than one clinic to collect the eGISP samples, 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 eGISP data manager. Any changes in participating clinics should be communicated to the eGISP data manager. |
| GISP_SPEC_ID | [Char, 13] | GISP ID | e.g., NYC-201703-07 | To maintain consistency for sentinel sites who are also funded for GISP activities, isolates from the first 25 male patients with gonococcal urethritis will be considered "GISP isolates"; therefore, eGISP sites that are also GISP sites should assign and maintain a GISP ID locally constructed by |

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|-----------------------|-------------|------------------------------------|---|--|
| | | | | concatenating the variables of sentinel site code+year month+GISP isolate ID number, separated by hyphens. |
| PATIENT_GENDER | [Char, 1] | Patient Gender | 1=male 2=female 3=trans male 4=trans female 5=non-binary/trans other 9=unknown | |
| ETHNIC | [Char, 1] | Hispanic | 1=Hispanic or Latino 2=not Hispanic or Latino 9=unknown | 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, <i>note that race and ethnicity are not mutually exclusive variables.</i> 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. |
| AMIND | [Char, 1] | American Indian/ Alaskan Native | 1=yes, 2=no, 9=unknown | It is important to be as precise as possible with regard to demographic data as it may be used as an |

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|----------------|-------------|--------------------------------------|--------------------------------|--|
| ASIAN | [Char, 1] | Asian | 1=yes, 2=no, 9=unknown | <p>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.</p> |
| BLACK | [Char, 1] | Black | 1=yes, 2=no, 9=unknown | |
| NAHAW | [Char, 1] | Native Hawaiian/ Pacific Islander | 1=yes, 2=no, 9=unknown | |
| WHITE | [Char, 1] | White | 1=yes, 2=no, 9=unknown | |
| ORACE | [Char, 1] | Other race | 1=yes, 2=no, 9=unknown | |
| DATEVIS | [Date] | Date of clinic visit | MM/DD/YYYY | |
| AGE | [Num, 2] | Age in years | 1, 2, 3...98 99=unknown | |
| CISFEM | [Char, 1] | Cis female partners | 1=yes, 2=no, 9=unknown | Gender of the patient's sexual partners within |

| Variable Name | Type/Length | Description | Values | Comments |
|------------------|-------------|--|--|--|
| | | | | <p>the past 3 months. You should respond "yes" for all gender categories that apply.</p> <p>In clinics where gender of sex partner is not directly ascertained from the patient, you should respond "yes" for "female partners (unknown gender)" and/or "male partners (unknown gender)" categories that apply. In clinics where sex or gender of sex partner is not directly ascertained from the patient, code "9" for "unknown" in the cis and trans partner categories.</p> |
| CISMALE | [Char, 1] | Cis male partners | 1=yes, 2=no, 9=unknown | |
| TRANSFEM | [Char, 1] | Trans female partners | 1=yes, 2=no, 9=unknown | |
| TRANSMALE | [Char, 1] | Trans male partners | 1=yes, 2=no, 9=unknown | |
| UNKFEM | [Char, 1] | Female partners (unknown gender) | 1=yes, 2=no, 9=unknown | |
| UNKMALE | [Char, 1] | Male partners (unknown gender) | 1=yes, 2=no, 9=unknown | |
| SYMP | [Char, 1] | Presence of gonorrhea symptom(s) at anatomic site of isolate | 1=symptoms present 2=no symptoms present 9=unknown | <p>This question pertains to the presence of symptoms of gonorrhea at the genital and/or extra-genital site where the isolate was collected. Symptoms of gonorrhea include the following:</p> <ul style="list-style-type: none"> - Urethral infection: urethral discharge and/or dysuria (pain with urination) - Endocervical infection: vaginal discharge and/or dysuria - Rectal infection: rectal discharge, rectal pain, and/or tenesmus (pain with passing bowel movements) - Pharyngeal infection: sore throat |

| Variable Name | Type/Length | Description | Values | Comments |
|----------------|-------------|---|--|--|
| | | | | If there are no data in the record regarding the presence OR absence of gonorrhea symptoms as described above, code this field "9" indicating "unknown symptomatology." |
| HISTORY | [Char, 1] | Previous history of gonorrhea (ever) | 1=yes 2=no 9=unknown | 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." |
| EPSDS | [Num, 2] | Number of previous episodes within the past 12 months | 0=no documented episodes 99=unknown | Enter the number of previous episodes of gonorrhea documented in the patient's record within the past 12 months. |
| HIVSTAT | [Char, 1] | HIV status at time of clinic visit for gonorrhea | 1=positive 2=negative 3=indeterminate 9=unknown | 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. 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." |
| TRAVEL | [Char, 1] | Travel outside of US in past 60 days | 1=yes | 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 |

| Variable Name | Type/Length | Description | Values | Comments |
|-----------------|-------------|--|----------------------------|---|
| | | | 2=no 9=unknown | did not travel internationally during the previous 60 days. If travel information is not available, code "9" for "unknown." |
| SEXWK | [Char, 1] | History of giving or receiving drugs/money in the past 12 months | 1=yes 2=no 9=unknown | 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. |
| ANTIBIOT | [Char, 1] | Antibiotic use in the past 60 days | 1=yes 2=no 9=unknown | 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. |
| IDU | [Char, 1] | History of injection drug use in the past 12 months | 1=yes 2=no 9=unknown | 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 12 months. 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. |

| Variable Name | Type/Length | Description | Values | Comments |
|---------------|-------------|---|--|---|
| NONIDU | [Char, 1] | History of non-injection drug use in the past 12 months | 1=yes 2=no 9=unknown | 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 12 months. 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. |
| TRMT1 | [Char, 2] | Primary treatment for gonorrhea | 00=none 03=spectinomycin (Trobicin) 2 gm 04=ceftriaxone (Rocephin) 250 mg 05=ceftriaxone (Rocephin) 125 mg 06=ciprofloxacin (Cipro) 500 mg 07=cefoxitin (Mefoxin) 2 gm 12=cefixime (Suprax) 400 mg 14=cefepodoxime proxetil (Vantin) 200 mg 15=ofloxacin (Floxin) 400 mg 17=ceftizoxime (Cefizox) 500 mg 18=cefotaxime (Claforan) 500 mg | Indicate the primary antimicrobial prescribed to treat the case of gonorrhea. 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. NOTE: New Gonorrhea Treatment Recommendations choices. 29: Ceftriaxone 500 mg 30: Ceftriaxone 1g 31: Cefixime 800 mg |

| Variable Name | Type/Length | Description | Values | Comments |
|-----------------|-------------|--|---|---|
| | | | 21=azithromycin (Zithromax) 2 gm 22=levofloxacin (Levaquin) 250 mg 23=cefepodoxime 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) 29=Ceftriaxone 500 mg 30=Ceftriaxone 1g 31=Cefixime 800 mg 88=other (please indicate in Other Treatment 1) 99=unknown | |
| OTHTRMT1 | [Char, 15] | Other treatment not listed as code for TRMT1 | If code "88" was entered for Treatment 1, please type in the name and dosage of the drug used for primary treatment of gonorrhea. | If code "88" ("other") was entered for Treatment 1, write in the name and dosage of the primary antimicrobial therapy for gonorrhea and dosage that was administered. |
| TRMT2 | [Char, 2] | Second antibiotic used as part of dual | 00=none | In many cases, two antibiotics may be prescribed for patients diagnosed with gonorrhea. Dual therapy |

| Variable Name | Type/Length | Description | Values | Comments |
|---------------|-------------|--|---|---|
| | | therapy for gonorrhea (and treatment of chlamydia) | 01=ampicillin/amoxicillin 09=doxycycline (Vibramycin)/ tetracycline 10=erythromycin 11=azithromycin (Zithromax) 1 gm 15=ofloxacin 21=azithromycin (Zithromax) 2 gm 22=levofloxacin 88=other 99=unknown | (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. 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. |