

Gonococcal Isolate Surveillance Project

OMB 0920-0307

Sancta St. Cyr, Project Officer

Attachment 7

Data Coding Guide

Core Clinical/Demographic Data Elements

Variable Name	Type/Length	Description	Values	Comments
CLINIC	[Char, 3]	Sentinel site code	ALB = Albuquerque ATL=Atlanta BHM=Birmingham BOS=Boston CHI=Chicago COL=Columbus CLE=Cleveland DAL=Dallas FSM =Federated States of Micronesia GRB=Greensboro HON=Honolulu IND=Indianapolis KAZ=Kalamazoo KCY=Kansas City LVG=Las Vegas LA1/LA2=Los Angeles MIA=Miami MIN=Minneapolis NOR=New Orleans ORA=Orange County PHI=Philadelphia PHX=Phoenix PON=Pontiac POR=Portland SDG=San Diego SFO=San Francisco TRP=Triplern	
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.
DATEVIS	[Char, 10]	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

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				correspond to the year and month entered for item 2 above.
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 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	
AGE	[Num, 2]	Age in years	1, 2, 3...98 99=unknown	
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 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.
ASIAN	[Char, 1]	Asian	1=yes, 2=no, 9=unknown	
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	
ETHNIC	[Char, 1]	Hispanic	1=Hispanic or Latino 2=not Hispanic or Latino 9=unknown	

Variable Name	Type/Length	Description	Values	Comments
				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.
CISFEM	[Char, 1]	Cis female partners	1=yes, 2=no, 9=unknown	<p>Gender of the patient's sexual partners within 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."</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	
UNK	[Char, 1]	Unknown	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 <p>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."</p>

Variable Name	Type/Length	Description	Values	Comments
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 2=no 9=unknown	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."
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.

Variable Name	Type/Length	Description	Values	Comments
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 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.
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 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.
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=cefpodoxime proxetil (Vantin) 200 mg 15=ofloxacin (Floxin) 400 mg 17=ceftizoxime (Cefizox) 500 mg 18=cefotaxime (Claforan) 500 mg 21=azithromycin (Zithromax) 2 gm 22=levofloxacin (Levaquin) 250 mg 23=cefpodoxime proxetil (Vantin) 400 mg 24=ceftibuten (Cedax) 400 mg	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.

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			25=cefdinir (Omnicef) 300 mg 26=cefdinir (Omnicef) 600 mg 27= gemifloxacin 320 mg 28= gentamicin 240 mg (or weight-based dosage) 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 One, 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 therapy for gonorrhea (and treatment of chlamydia)	00=none 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	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.

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).
SURRG_SPEC_ID	[Char, 18]	SURRG/eGISP ID	e.g., CHICC170107918.	For all isolates collected, sites should assign and maintain an SURRG/eGISP 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 isolate collection	U=urethral V=vaginal E=endocervical UR=urine R=rectal P=pharyngeal B=blood C=conjunctival O=other NC=not captured	Blood and/or conjunctival specimens are not expected to be collected as part of eGISP.
NAAT_GC	[Char, 1]	Nucleic acid amplification test (NAAT) result	1=positive 2=negative 3=indeterminate 9=unknown	
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".