

Gonococcal Isolate Surveillance Project

OMB 0920-0307

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Attachment 8

Justification for Collection of Sensitive Data

There are sensitive questions included in Demographic/Clinical data collected from all sentinel sites participating in GISP core and enhanced activities. These are elicited at participating STD clinics in a private environment and recorded by STD clinicians in order to assess behavioral and biological risk of infection, to guide appropriate behavioral counseling, and to determine the appropriate anatomic sites for STD testing or screening. These items are asked for all STD infections and not specifically for GISP. These sensitive questions are essential in order to develop an accurate surveillance picture of disease in the community and to provide appropriate clinical care for each patient. These questions have been critically important for GISP in identifying epidemiological risk factors for antibiotic resistant gonorrhea. The table below outlines the justification for each question.

Attachment #	Question	Justification for question
Attachment 3a1 & Attachment 3a2	Gender (sex) of sex partner	Collecting information on gender (sex) of sex partner helps identify patients at increased risk of gonorrhea and increased risk for acquisition of resistant strains. Men who have sex with men are at elevated risk for acquisition of resistant strains of <i>N. gonorrhoeae</i> . ¹⁻³
Attachment 3a1 & Attachment 3a2	Previous history of gonorrhea (ever); number of previous episodes within the past 12 months	Collecting information on prior gonococcal infections is useful in determining whether antimicrobial resistance is more likely to emerge in core groups of individuals who have frequent gonococcal infections and are treated with antimicrobials frequently. ⁴
Attachment 3a1 & Attachment 3a2	HIV status at time of clinic visit for gonorrhea	Collecting on HIV status is useful for identifying increased transmission of resistant strains among certain immunosuppressed populations who may be engaging in risky sexual behavior. As

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		data from GISP have demonstrated, HIV infection in some men might be a marker of heightened risk for acquisition of resistant <i>N. gonorrhoeae</i> strains. ³
Attachment 3a1 & Attachment 3a2	Travel outside of US in past 60 days	Collecting information on recent travel outside the US is useful in determining whether antimicrobial resistance is more likely to emerge imported. ⁴
Attachment 3a1 & Attachment 3a2	History of giving or receiving drugs/money in the past 12 months	Collecting information on history of giving or receiving drugs/money in the past 12 months helps identify patients at increased risk of gonorrhea. ⁵
Attachment 3a1 & Attachment 3a2	Antibiotic use in the past 60 days	Collecting information on recent antibiotic use is useful in determining whether antimicrobial resistance is more likely to emerge in individuals recently treated with antimicrobials. ^{4,5}
Attachment 3a1 & Attachment 3a2	History of injection drug use in the past 12 months; History of non-injection drug use in the past 12 months	Collecting information on recreational drug use in the past 12 months helps identify patients at increased risk of gonorrhea. ⁵

References

1. Kirkcaldy RD, Zaidi A, Hook EW III, et al. *Neisseria gonorrhoeae* Antimicrobial Resistance Among Men Who Have Sex With Men and Men Who Have Sex Exclusively With Women: The Gonococcal Isolate Surveillance Project, 2005-2010. *Annals Intern Med* 2013;158(5):321-8.
2. Kirkcaldy RD, Bolan GA, Wasserheit JN. Cephalosporin-Resistant Gonorrhea in North America. *JAMA* 2013;309(2):185-187.
3. Kirkcaldy RD et al. *Neisseria gonorrhoeae* antimicrobial susceptibility among men by HIV status, Gonococcal Isolate Surveillance Project (GISP), 2010-June 2014 (abstract 1338). National HIV Prevention Conference, December 8, 2015. Atlanta, GA.
4. Zenilman JM et al. Penicillinase-producing *Neisseria gonorrhoeae* in Dade County, Florida: Evidence of core-group transmitters and the impact of illicit antibiotics. *Sex Transm Dis* 1988;15(1):45-50.
5. Hook EW III et al. Determinants of emergence of antibiotic-resistant *Neisseria gonorrhoeae*. *J Infect Dis* 1989;159(5):900-7.