

Gonococcal Isolate Surveillance Project

OMB 0920-0307

Sancta St. Cyr, Project Officer

Attachment 9

Changes to the Information Collection

The following changes have been made to the information collection (IC):

- 1) Collection of additional *Neisseria gonorrhoeae* isolates and additional epidemiology data elements from a subset of sentinel sites
 - a. A summary of the enhanced data collection has been added to Supporting Statement A, under the section titled *Justification* on page 4.
 - b. Explanation of how burden hours were calculated has been added to Supporting Statement A, under the section titled *Estimated Annualized Burden Hours and Costs* starting on page 13.
 - c. Supporting Statement A, Table A.12-1: Estimated Annualized Burden Hours has been updated on page 16.
 - d. Supporting Statement A, Table A.12-2: Estimated Annualized Burden Costs has been updated on page 16.
 - e. Addition of the updated data collection files
(Attachment 3a2, Attachment 3b)
- 2) Identification of bacterial isolates that appear to be *N. gonorrhoeae* by routine laboratory testing but are actually a different kind of bacteria
 - a. A summary of the enhanced data collection has been added to Supporting Statement A, under the section titled *Justification* on page 5.
 - b. Explanation of how burden hours were calculated has been added to Supporting Statement A, under the section titled *Estimated Annualized Burden Hours and Costs* starting on page 13.
 - c. Supporting Statement A, Table A.12-1: Estimated Annualized Burden Hours has been updated on page 16.
 - d. Supporting Statement A, Table A.12-2: Estimated Annualized Burden Costs has been updated on page 16.
- 3) Reduction in the burden of testing and reporting control strains at regional laboratories
 - a. A summary of change in control strain testing and explanation of how burden hours were calculated has been added to Supporting Statement A, under the section titled *Estimated Annualized Burden Hours and Costs* starting on page 13.
 - b. Supporting Statement A, Table A.12-1: Estimated Annualized Burden Hours has been updated on page 16.

- c. Supporting Statement A, Table A.12-2: Estimated Annualized Burden Costs has been updated on page 17.
- 4) Increase in testing volume of the regional laboratories.
 - a. A summary of change in antimicrobial susceptibility testing and explanation of how burden hours were calculated has been added to Supporting Statement A, under the section titled *Estimated Annualized Burden Hours and Costs* starting on page 13.
 - b. Supporting Statement A, Table A.12-1: Estimated Annualized Burden Hours has been updated on page 16.
 - c. Supporting Statement A, Table A.12-2: Estimated Annualized Burden Costs has been updated on page 17.

Why changes have been made to the information collection

The Gonococcal Isolate Surveillance Project (GISP) is the only national and regional surveillance system that monitors *Neisseria gonorrhoeae* antimicrobial susceptibility. Because *N. gonorrhoeae* resistance continues to emerge and fewer antimicrobial drugs are being brought to market, GISP is a critically important surveillance system. The project aims to continue to improve the way that surveillance is conducted. GISP has consistently provided robust data that allow monitoring of resistance trends and inform updates to treatment guidelines. However, GISP samples <4% of reported male gonorrhea cases in the United States. This relatively limited scope likely limits the speed with which new resistance patterns are found and with which public health officials can respond. Expanding the number of isolates collected in GISP is expected to allow public health officials to detect and respond to resistance more quickly. In addition, GISP only samples urethral isolates. Published data suggest that resistance in *N. gonorrhoeae* might develop initially in non-genital anatomic sites, such as the pharynx. Including isolates from the pharynx and other anatomic sites is expected to also support public health efforts to detect and respond to resistance more quickly. To best interpret the data, collection of additional data elements is necessary (**Attachment 3a2**). Data on anatomic site of infection and unique assigned (but without personal identifying information) patient identifiers are critical for analyzing and making sense of the data: if >1

isolate came from a single patient, that information should be incorporated into how data analyses are performed.

GISP surveillance can also be strengthened by ensuring that GISP surveillance is only being conducted on *N. gonorrhoeae* and not on other similar bacteria that can cause indistinguishable syndromes, such as *Neisseria meningitidis*. Collecting additional data on specialized laboratory testing that can tell the difference between these bacteria will allow GISP to exclude other non-gonococcal bacteria from the data, strengthening the accuracy and usefulness of GISP data. Collecting limited demographic and epidemiological data (**Attachment 3a2**) on these other infections will allow GISP to better define the populations affected and risk factors for these infections and better exclude these infections from GISP surveillance in the future.

The number of control strains that are included in each control strain set will be reduced from 7 to 3 and laboratories will no longer be required to report control strain results. This procedure will better align with guidance from entities that oversee laboratory testing practices in the United States and will provide greater clarity to the regional laboratories about when a testing run needs to be repeated.

How changes will affect the information collection

Sentinel sites that voluntarily apply and are awarded additional funding for enhanced data and specimen collection will be asked to collect additional gonococcal isolates and collect (from the medical record) additional epidemiological data elements about persons from whom isolates were collected (**Attachment 3a2**). Collection of additional isolates and data elements will increase the total burden hours (Table A.12-1) for the sentinel sites from 1,320 to 2,560. The annualized burden costs (Table A.12-2) will increase from \$21,291.60 to \$52,056. The increase in burden cost includes an adjustment (increase) in the estimated average hourly wage, from \$16.13 to \$19.28.