

Gonococcal Isolate Surveillance Project

OMB 0920-0307

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Attachment 9

Changes to the Information Collection

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

- 1) Collection of *Neisseria gonorrhoeae* positive remnant nucleic acid amplification test (NAAT) specimens and associated epidemiology data elements from a subset of sentinel sites
 - a. A summary of the new enhanced molecular surveillance activity 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 14.
 - c. Supporting Statement A, Table A.12-1: Estimated Annualized Burden Hours has been updated on page 17.
 - d. Supporting Statement A, Table A.12-2: Estimated Annualized Burden Costs has been updated on page 18.

- 2) Update to the data element choices for treatment received currently collected for all GISP sentinel sites
 - a. A summary of the change to the data elements collected in GISP has been added to Supporting Statement A, under the section titled *Justification* on page 4.
 - b. Addition of updated data coding guide (**Attachment 7**)

Why changes have been made to the information collection

The Gonococcal Isolate Surveillance Project (GISP) is the only national and regional sentinel 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 to inform updates to treatment guidelines.

Culture based gonococcal susceptibility testing methods, like agar dilution, have historically been used in national surveillance programs like GISP. These methods, however, are labor intensive and are limited to locations with gonococcal

culture capacity. Molecular based surveillance provides a culture independent method of determining antimicrobial resistance-conferring mutations. By using remnant NAAT specimens, surveillance of known resistance-conferring genetic mutations can be identified in locations not currently performing gonococcal cultures and can be performed on male and female genital and extragenital samples. Molecular surveillance does not replace current culture-based surveillance, but provides an opportunity to better characterize circulating resistance patterns and improve participation in national surveillance. Molecular surveillance is expected to also support public health efforts to detect and respond to resistance more quickly. To best interpret the data, collection of data elements associated with each submitted remnant NAAT specimen is necessary. The data elements are the same as the data elements collected under the current enhanced surveillance activity (**Attachment 3a2**).

In December 2020, CDC released the Update to CDC's Treatment Guidelines for Gonococcal Infection. These new treatment recommendations increased the dose of the recommended regimen and the dose for an alternative regimen (ceftriaxone and cefixime, respectively). These values, collected and recorded under the received treatment data element, are being added to allow for the collection of treatment data consistent with these updated recommendations.

How changes will affect the information collection

Sentinel sites that voluntarily apply and are awarded funding for the enhanced molecular surveillance activity will be asked to retain, freeze and ship remnant NAAT specimens directly to CDC for molecular characterization. In addition, they will be asked to submit epidemiological data elements about persons from whom remnant NAAT specimens were collected (**Attachment 3a2**). The total burden hours (Table A.12-1) for all the sentinel sites participating in molecular surveillance will be 1,680. The annualized burden costs (Table A.12-2) for all sentinel sites participating in molecular surveillance will be \$34,255. The burden cost is based on the estimated average hourly wage of \$20.39.