



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-21-0307 Docket No. CDC-2021-0017]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Gonococcal Isolate Surveillance Project (GISP)". The purpose of GISP is to monitor trends in antimicrobial resistance in *N. gonorrhoeae* strains in the United States in order to establish a scientific basis for the selection of gonococcal therapies and to allow proactive changes to treatment guidelines before widespread resistance and failures of treatment occur.

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No.

CDC-2021-0017 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also

requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

## Proposed Project

Gonococcal Isolate Surveillance Project (OMB Control No. 0920-0307, Exp. 8/31/2021) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

The Gonococcal Isolate Surveillance Project (GISP) was created in 1986 to monitor trends in antimicrobial susceptibilities of *Neisseria gonorrhoeae* strains in the United States. GISP continues to be a collaboration between different branches of the CDC's Division of STD Prevention, selected regional laboratories and selected state/local public health departments and their associated STD specialty care clinics in the United States. National organizations, local jurisdictions and individuals use data collected in GISP to understand, monitor, and prevent further transmission of antibiotic resistant strains of *N. gonorrhoeae*. Data from GISP are used to establish a scientific basis for the selection of gonococcal therapies and to allow pro-active changes to treatment guidelines before widespread resistance and failures of treatment occur. To increase capacity to detect and monitor resistant gonorrhea and to improve the specificity of GISP, this revision is being submitted to include collection of remnant nucleic acid amplification test (NAAT) specimens and updated

data element options for treatment received based on the 2020 updated gonorrhea treatment recommendations.

GISP core surveillance activities sample <4% of reported male gonorrhea cases in the United States and are limited to urethral infections only. In 2018, enhanced GISP (eGISP) began sampling female genital (endocervical and vaginal) and male and female extragenital (pharyngeal and rectal) anatomic sites, in addition to the male genital site already sampled in GISP core surveillance. Including isolates from the pharynx and other anatomic sites, as well as from women, expands on GISP's public health efforts to detect and respond to resistance more quickly. GISP surveillance was also strengthened with the addition of eGISP by identifying isolates that are culture positive for *N. gonorrhoeae*, but negative by NAAT, which is a more specific diagnostic test. This helped to ensure that non-gonococcal bacteria are excluded from gonococcal data, strengthening the accuracy and usefulness of GISP data, especially when clinical syndromes with other *Neisseria species* are indistinguishable from gonorrhea.

To further improve and strengthen GISP surveillance, an additional enhanced surveillance activity in the form of molecular surveillance has been added to this revision. Participating sites already locally performing NAATs would retain the leftover gonorrhea-positive samples (remnant) after diagnostic results have been determined and reported as part of standard care. The gonorrhea-positive remnant NAAT sample would

be frozen, stored and then shipped directly to CDC on a monthly basis for molecular characterization of known resistance-conferring gene mutations. Remnant NAAT specimens from any anatomic site (including from the urethra, pharynx, rectum, vagina and cervix) of gonorrhea positive persons will be accepted. We anticipate that 10 sites will participate in this molecular surveillance activity and we anticipate up to ~70 positive remnant NAAT specimens per month will be sent by each of these 10 sites to CDC for testing.

To maintain accurate collection of GISP data elements, this revision also includes the updated weight-based dosing of ceftriaxone and cefixime. 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.

Under this revision, the data collection and processes for all GISP activities are unchanged. The increased dosages for ceftriaxone and cefixime treatments allow for new data element options, but not a change in the number of data elements or the current work demand to collect them. All demographic/clinical data from the sentinel sites will be submitted electronically directly from the sentinel sites to the GISP data manager at CDC

through; (1) a secure data portal, or (2) through the CDC Secure Access Management Services partner portal. To minimize burden, comma-separated values (csv) files that provide standardized structure of the electronic data are provided to sentinel sites and laboratories. Additionally, to further minimize burden, the regional laboratories will be able to extract electronic data directly from electronic laboratory information systems instead of hand entering data. Laboratories are not required to report control strain testing results.

This project will not collect name, social security number, or date of birth. A Patient ID, a unique patient identifier assigned by the site that allows for linking of multiple isolates from a single person at a single clinic visit and across multiple clinic visits, is requested and will be provided to CDC for purposes of enhanced surveillance. Sensitive information such as sex of sex partners, HIV status, sex work exposure, and injection drug use are collected. Patient data are obtained through review of medical records by the clinic staff and included in collection reporting of demographic/clinical information. All personally identifiable information (PII) is retained by the STD clinics that treated the patient and is not recorded with data sent to CDC or regional laboratories. The electronic GISP database is stored on the CDC mainframe computer and only approved Division of STD Prevention (DSTDP) staff have access rights to the data. As part of the revision, we will continue to systematically identify the risks and potential

effects of collecting, maintaining, and disseminating PII and to examine and evaluate alternative processes for handling that information to mitigate potential privacy risks and risks to confidentiality.

The CDC has designated *N. gonorrhoeae* as one of five “urgent” antibiotic resistance threats in the United States. The CDC is requesting a three-year OMB approval for this revision, which directly responds to the National Strategy for Combating Antibiotic Resistant Bacteria by improving and strengthening surveillance of antimicrobial resistance through GISP. GISP data can help monitor and evaluate the effectiveness of public health interventions conducted to support the National Strategy for Combating Antibiotic Resistant Bacteria. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Sentinel site conducting culture-based core surveillance	Demographic/Clinical Data (Attachment 3a1)	20	240	11/60	880
Sentinel site conducting culture-based enhanced surveillance	Demographic/Clinical Data (Attachment 3a2)	10	840	12/60	1,680
Sentinel site conducting molecular	Demographic/Clinical Data (Attachment 3a2)	10	840	12/60	1,680

enhanced surveillance					
Regional laboratory	Antimicrobial Susceptibility Testing Results (Attachment 3b)	4	3,300	40/60	8,800
	Control Strain Susceptibility Testing		48	5/60	16
Total		44			13,056

**Jeffrey M. Zirger,**

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