



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-25-25CH; Docket No. CDC-2024-0102]

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 information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS). CARGOS is a comprehensive strategy designed to streamline and improve the coordination of Antimicrobial Resistance (AR) surveillance and preparedness and response activities focused on *Neisseria gonorrhoeae* (GC) and expand capacity to include other STIs with emerging AR in the United States.

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-2024-0102 by either of the following methods:

- Federal eRulemaking Portal: www.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, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.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, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 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 the 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;

4. Minimize the burden of collecting information on those to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic responses; and
5. Assess information collection costs.

Proposed Project

Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS) – New – National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of the proposed Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS) data collection is to: (1) strengthen local epidemiologic capacity to detect, monitor, and respond to AR in STIs; (2) improve coordination of AR in STI preparedness and outbreak response activities; (3) enhance local laboratory testing for surveillance, reporting, and response; and (4) enhance coordination between epi-lab-health information technology for public health action. This information collection is important because: (1) effective treatment of gonorrhea is critical to gonorrhea control and prevention; (2) untreated or inadequately treated gonorrhea can cause serious reproductive health complications, such as infertility; (3) *Neisseria gonorrhoeae* (the bacterium that causes gonorrhea) has consistently demonstrated the ability to develop resistance to the antibiotics used for treatment and may be developing resistance to the last remaining treatment option recommended by CDC; and (4) antibiotic-resistant gonorrhea is extremely difficult to detect without enhanced surveillance and public health activities, such as CARGOS, because healthcare providers rarely perform or have access to resistance testing for individual patients. CARGOS will support rapid detection of resistant gonorrhea, get actionable information into the hands of healthcare providers (to support appropriate treatment of individual patients) and local health departments (to support rapid public health response to slow the spread of resistant infections in the community), and support multiple national public health strategies

including the 2020–2025 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) and STI National Strategic Plan for the United States 2021–2025.

Jurisdictions participating in CARGOS applied as part of a competitive process and will participate voluntarily. As an overview of CARGOS, healthcare providers at participating clinics will collect specimens for *N. gonorrhoeae* culture testing from men and women seeking care for gonorrhea. Specimens that demonstrate *N. gonorrhoeae* (called “isolates”) will undergo antibiotic resistance testing at the local public health laboratory. Detection of resistance is rapidly communicated by the laboratory staff to the healthcare provider and health department to initiate a field investigation. The patient (from whom the resistant specimen was taken) will be interviewed to obtain demographics, clinical and risk factor information. For cases of gonorrhea of public health significance, recent sexual contacts of those cases will be interviewed by the health department and tested for gonorrhea. The participating health departments will collect and transmit to CDC demographic and clinical data about persons tested for and diagnosed with gonorrhea in the participating clinics, results of local antibiotic resistance testing, and information about field investigations. None of the data transmitted to CDC will contain any personally identifiable information. These data will be used by CDC to monitor and improve understanding of resistance and identify scalable, effective approaches to prevent the spread of resistance. Data will be transmitted through CDC’s Secure Access Management Services (SAMS). SAMS is an approved federal information technology system that provides authorized and validated users secure and encrypted access to CDC file transfer applications. The encrypted data will be stored in a secure CDC server with strictly controlled and restricted access rights. Isolates will be shipped each month to one of four Antibiotic Resistance Regional Laboratory Network (ARLN) laboratories for confirmatory antibiotic susceptibility testing and molecular characterization.

Under the CARGOS protocol, local CARGOS data managers from each of the funded jurisdictions will abstract STD clinic data for patients tested for gonorrhea, receive resistance

testing laboratory results from local public health laboratories, abstract data about field investigations, and will merge the data. Every month, the local CARGOS data manager will clean the data, remove personally identifiable information, and transmit the data to CDC. CDC estimates these data processes will take eight hours every month. Annually, the local CARGOS data manager will send a final cumulative data file for a total of 12 data transmissions/responses.

Microbiologists at public health laboratories from each funded jurisdictions will conduct antibiotic resistance testing on all *N. gonorrhoeae* isolates on approximately 700 isolates each year (600 clinical isolates and 100 control strains; each test is approximately 10 minutes). Every month, a laboratory data manager will abstract test results and securely send the datafile to the local CARGOS data manager. We estimate that laboratory data managers will spend approximately one hour each time they abstract, clean, and transmit project data.

Health department staff will interview any person diagnosed with antibiotic-resistant gonorrhea or have a case of gonorrhea of public health significance (index case) and his/her sexual contacts. On average, two drug-resistant isolates are identified annually. These isolates will spur field investigations, which will result in two additional interviews each month. CDC estimates a total of 48 interviews will occur annually at each site, for a total of 960 interviews each year across the funded sites. Each interview will take approximately 30 minutes.

CDC requests OMB approval for an estimated 3,875 annual burden hours. Respondents receive federal funds to participate in this project. There are no additional costs to respondents other than their time.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Public Health Laboratory Microbiologist	Attachment 3A	19	700	10/60	2,217
Public Health Laboratory Data Manager	Attachment 3A	19	6	1	114

Local CARGOS data manager/epidemiologist	Attachments 3A, 3B, 3C	19	7	8	1,064
Gonorrhea Patients and Sexual Contacts	Attachment 3C	960	1	0.5	480
Total					3,875

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Public Health Ethics and Regulations,

Office of Science,

Centers for Disease Control and Prevention.

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